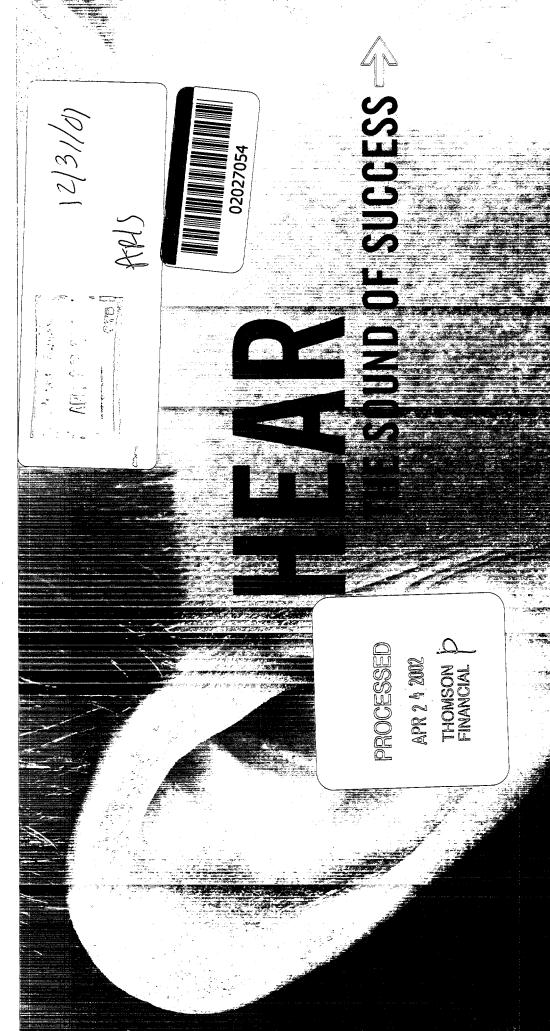
SYMPHONIX 2001 ANNUAL REPORT





"MY FIRST EXPOSURE TO A SOUNDBRIDGE PATIENT WAS THAT SHE HEARD SO WELL THAT SHE COULD NOT WAIT FOR THE SECOND EAR TO BE IMPLANTED."

- Donna Seagal, Audiologist, Indiana University "FOR PATIENTS WITH MILD TO SEVERE HEARING LOSSES, THIS IS THE ONLY DEVICE THAT IS ALWAYS USED BY MY PATIENTS!"

- Captain 'Fred' Lassen, USN, M.D., Portsmouth Naval Hospital "OUR RESEARCH IN STEREDAUDIOMETRY AT THE ROGER SALENGRO HOSPITAL IN LILLE CONFIRMS THAT THE VIBRANT SOUNDBRIDGE IS EVEN BETTER FOR COMMUNICATION IN TWO EARS THAN IN ONE AS ONE WOULD EXPECT. WHAT WE HAVE ALSO ESTABLISHED WITH OUR PATIENTS IS THAT THE SOUND QUALITY THROUGH ONE VSB IS BETTER THAN THROUGH ONE CONVENTIONAL HEARING AID."

- Prof. François Vaneecloo, Roger Salengro Hospital, Lille "PATIENTS REPORT CLEARER AND MORE NATURAL. HEARING WITH THE SOUNDBRIDGE AS COMPARED TO THEIR HEARING AIDS."

- Gary W. Mears, COO, Hear America, Inc., Missouri "SINCE WE COMMENCED IMPLANTING THE SOUND-BRIDGE AT THE CAUSSE CLINIC, DEMAND FOR THE DEVICE HAS LEAD TO SCHEDULE 1-2 SURGERIES PER WEEK FOR THE REST OF THE YEAR."

 Prof. Thibaud Dumon, M.D., Clinique J. Causse, Beziers





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Otology and audiology partnerships are critical to our long-term success.

tices and audiology practices and will continue this effort in 2002 and beyond. We have designated these partners "Symphonix Centers of Excellence" for their successful efforts in adopting the Vibrant Soundbridge into their practices and for their commitment to quality of care and overall satisfaction for their patients. We look forward to working with these **OVER THE COURSE OF 2001** we established partnerships with many otology prac-"Symphonix Centers of Excellence" for many years.

hearing aids. These programs have begun to have a positive result as Siemens received its largest Vibrant Soundbridge order ever (fifty units) from a top tor in Europe, Siemens is investing in market development programs to create broad awareness of the Vibrant Soundbridge as an alternative to acoustic hearing clinic in France. Siemens has also introduced us to many of their significant audiology customers in the U.S. thus, providing a key bridge to Our partnership with Siemens continues to provide benefits. As our distribuaccess successful audiology practices in the U.S. Having access to Siemens' leading edge digital signal processing technology allowing us to continue to provide our patients with the latest and best allows us to be on the cutting edge of hearing electronics technology, thus, technology available. Having Siemens' digital signal processing technology ogy customers because Siemens' software to program the digital signal in our product also allows us a positive entry point with prospective audiolprocessor is well established in the audiology community,

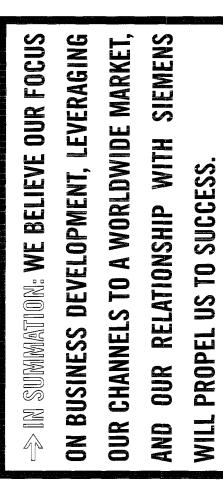














COMPETITIVE ADVANTAGE INTELLECTUAL PROPERTY POSITION. THIS WILL ENSURE A LONG-TERM BELIEVE SYMPHONIX'S PATENTS PROVIDE A UNIQUE seeking reimbursement from private insurance carriers. We believe our product as a surgically implanted device with clinically proven benefits lends itself to satisfying many of the criteria needed for reimbursement. At this point, we have had success with a number of cases being either partially or fully reimbursed by private insurance carriers. We have added internal resources to support prospective patients and physicians in applying for insurance coverage.

cessfully transitioned to Siemens and Siemens' country level distribution groups incorporated were in France where our product has been well accepted by otologists, audiologists and the hearing impaired. We have also established a strong franchise with the Causse Clinic in Beziers, France, which is the largest private otolaryngology clinic in France. With Siemens as our distribution partner we continue to make inroads in Germany, Switzerland, and Austria. Consistent with our efforts towards reimbursement in the U.S., we will be submitting reimbursement applications in France and each German province in 2002 with expected determination in mid-2003. In Switzerland, we are already having selected cases covered In addition to laying the market foundation in the U.S., we successfully transferred full distribution of our product in Europe to Siemens. Our country level sales representatives sucthe Vibrant Soundbridge into their product offering. Our largest number of unit sales in 2001

On the product development front, in late 2001 we introduced a new Audio Processor (AP), the model 404, which is now offered in a new robust multi-colored housing. The response from customers to this new AP has been very positive. We anticipate introducing another new AP in 2002 which will include directional microphones and enhanced cosmetics. We look forward to the many challenges we have in 2002 to continue to work toward greater Our product truly does change people's lives in the most positive of ways. I thank you for your continued support through the market turmoil and the declining value of our share price in 2001. We continue to focus on the execution of our market plan, which we believe will build adoption of the Vibrant Soundbridge by hearing care professionals and the hearing impaired. the foundation for a solid business and increased shareholder value.

ail bar

## WE HAVE SUCCESSFULLY

### ESTABLISHED SUCCESSFUL MODEL FOR REFERRAL NETWORKS.

OBTAINED PRIVATE INSURANCE COVERAGE FOR A NUMBER OF CASES IN THE U.S. TRANSITIONED FULL DISTRIBUTION OF OUR PRODUCT IN EUROPE TO OUR DISTRIBUTION PARTNER SIEMENS.

SHOWN PROGRESS IN OUR PRODUCT'S ACCEPTANCE THROUGHOUT FRANCE, AND MORE RECENTLY IN GERMANY, SWITZERLAND AND AUSTRIA.



# GENERATING MOMENTUM IN THE MARKETPLACE

Key initiatives in 2001 lead to a more focused sales and marketing plan for 2002

SYMPHONIX 2002 SALES AND MARKETING PLAN builds from what we learned in 2001, our first full year since FDA approval. Last year, we launched a number of major programs and then wrapped up the cycle with a large scale professional research study to measure the impact on the hearing care professional network that recommends the Vibrant Soundbridge to the consumer. Additionally, we added to our knowledge base by hiring a Reimbursement Director, and a new National Sales Director and Marketing Manager who both have in-depth experience with the independent audiology referral channel.

### THE KEY ELEMENTS OF OUR 2002 PLAN ARE:

- Geographically focused referral networks
- Improved professional education and brand image
- Reimbursement programs
- Patient seminars with motivated partners

The development of strong referral networks is key. In 2001, we created a business model that is a win-win situation for both the otologist and referring audiologists. By working together, they can offer the most advanced treatment for sensorineural hearing loss, and both can increase their practice revenues. This year, we will be building our business geographically around areas where we have motivated surgeons and a select group of referring audiology practices. We have developed a stronger sales model with better sales tools so we can more effectively educate and motivate the independent audiologist. Additionally, we will launch a Symphonix Audiology Brand Image Program to more broadly communicate our product message.

Third party insurance reimbursement is another critical new initiative. We now have a comprehensive Reimbursement Manual to support otology surgeons in obtaining insurance coverage. Results to date have been positive and we will be expanding this program in 2002. The fourth key element of our plan is patient education. In 2002, our patient seminar and public relations program will continue and now be supported by the reimbursement initiative and even better trained audiology partners.



2002 marketing programs :







**→** PATIENT SEMINARS







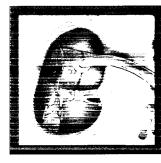


"WE HAVE BUILT A STRONGER SALES MODEL WITH BETTER SALES TOOLS TO MORE EFFECTIVELY EDUCATE AND MOTIVATE." DENNIS S. ROY, VICE PRESIDENT OF SALES AND MARKETING



Long term results show the outstanding benefits of the Vibrant Soundbridge continue over time.

### THE PATENTED FMT MECHANI-CALLY VIBRATES THE BONES OF THE MIDDLE EAR TO PRODUCE BETTER HEARING.



FMT in position on the ossicular chain.



The FMT is no larger than a grain of rice.

one year data, post FDA approval, shows that the Vibrant Soundbridge continues to be IME VIBRANT SOUNDBRIDGE is the first and only FDA approved implantable middle ear elimination of feedback and occlusion, (4) fantastic fit and comfort because the ear canal is left completely open and (5) outstanding cosmetics as compared to hearing aids. The Vibrant Soundbridge is made up of two components, the implanted portion or the Vibrating Ossicular Prosthesis<sup>174</sup> (VORP<sup>174</sup>) and the external portion or the Audio Processor<sup>nm</sup> (AP). The core technology is based on Symphonix's patented Floating Mass Transducer™ (FMT) which is attached to a bone in the middle ear. The AP picks up sound, transmits energy to the VORP and the FMT then mechanically vibrates the bones in the middle ear to mimic the natural hearing process. The surgical process for implanting the Vibrant Soundbridge is performed by an ear surgeon, an otologist, on an outpatient basis and takes roughly one to one and one half hours to complete. A number of weeks after surgery an audiologist, a hearing healthcare professional, custom programs the AP to the patient's hearing loss. The AP includes the latest eight channel digital signal processing technology from Siemens. As opposed to traditional acoustic hearing aids which have limited patient satisfaction, patients report overwhelming satisfaction with the Vibrant Soundbridge. We are proud to report that our first Vibrant Soundbridge patients implanted back in 1996 continue to be very satisfied users. Our hearing device for moderate to severe sensorineural hearing loss which provides: (1) improved sound quality and clarity, (2) increases in functional gain, (3) virtual a safe and effective treatment for moderate to severe sensorineural hearing loss.

# WE ARE BUILDING A NETWORK TO

EXPAND AWARENESS. IT CONSISTS OF

THREE CONSTITUENTS:

- DOTOLOGISTS
- **2) AUDIOLOGISTS**
- 3) HEARING IMPAIRED

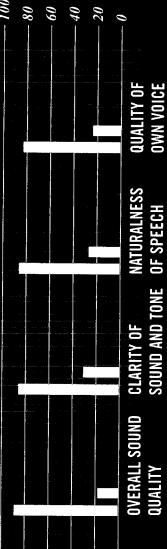
## N A P P P

PATIENT SATISFACTION WITH VIBRANT® SOUNDBRIDGE™ COMPARED TO HEARING AIDS (Percentage of satisfied / very satisfied)

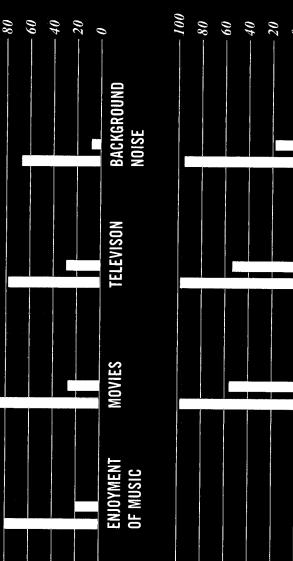
VIBRANT SOUNDBRIDGE

HEARING AIDS









IMPROVED COMFORT
AND MAINTENANCE

Source: Clinical trial results for the Fibrant Soundbridge; Otolaryngology-Head and Neck Surgery, Volume 126, No.2.

WHISTLING AND

CLEANING AND MAINTENANCE

FIT AND Comfort

FEEDBACK

## TO OUR SHAREHOLDERS:

DURING 2001

WE BUILT THE FOUNDATION IN THE U.S. FOR THE LONG-TERM SUCCESS OF THE VIBRANT SOUNDBRIDGE.

THROUGHOUT 2002 AND BEYOND WE WILL CONTINUE TO BUILD AWARENESS OF THE VIBRANT SOUNDBRIDGE AS A SAFE EFFECTIVE TREATMENT OPTION FOR ADULTS WITH MODERATE TO SEVERE HEARING LOSS SEEKING AN ALTERNATIVE TO ACOUSTIC HEARING AIDS.

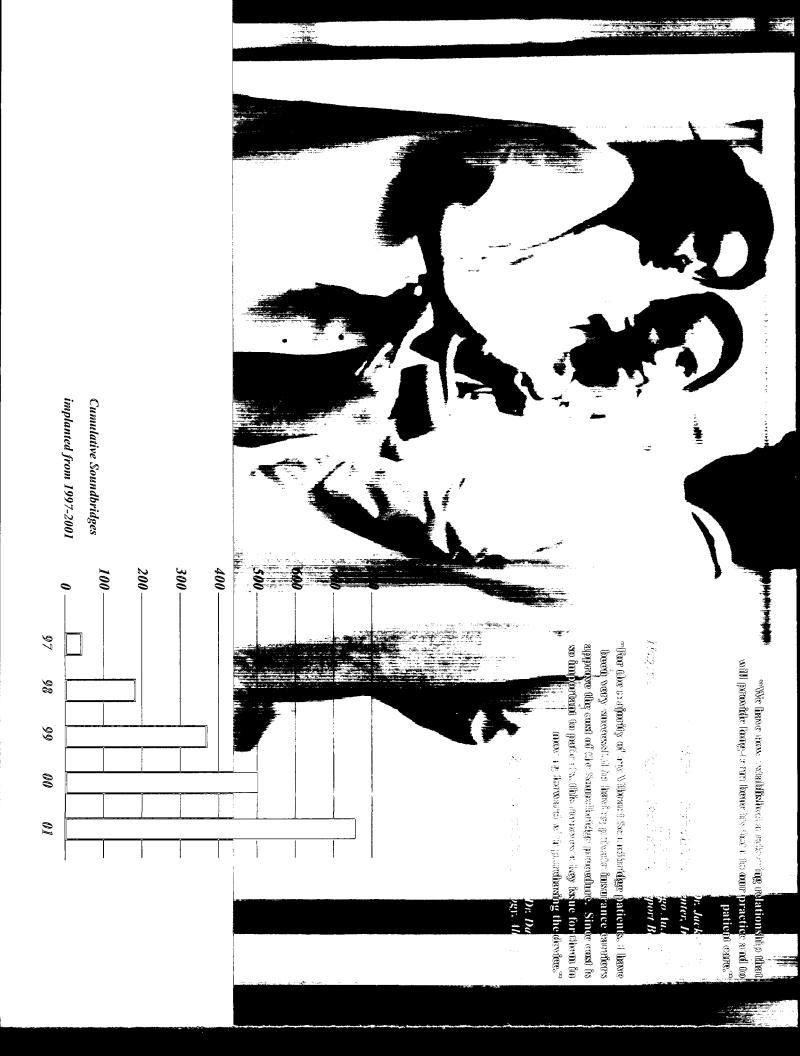
centers in the U.S. who would offer the Vibrant Soundbridge. In the later half of the year, our community such that otologists would incorporate the Vibrant Soundbridge into their practices stituents: otologists, audiologists and the hearing impaired. In the first half of the year, our Laying the market foundation involved a coordinated outreach effort to our three key conof building the foundation in the domestic market for our product, the Vibrant Soundbridge. introducing us to many of their significant audiology practice customers partners with the otologists. Our marketing partner, Siemens, has helped us in this effort by practices so they could offer the Vibrant Soundbridge to their patients and become referring focus was to build awareness of the product and its clinical benefits with key audiology initial focus was to build awareness of the product and its clinical benefits with the otology We were successful in building a core group of otology practices in all the major metropolitan THE YEAR 2001, our first full year of commercial availability in the United States, was a year

sponsor seminars in which the audiologist's patients were direct mailed and invited to a semiinar marketing initiative will continue into 2002. seminar attendance indicating there is very strong interest from current hearing aid users in nar to learn about the Vibrant Soundbridge. Response to the mailings generated favorable both in 2002 and beyond. Late in 2001, we began a program with our audiology partners to learning about middle ear implants and specifically, our product. The direct mailings and sem-While we have introduced the product to many audiology practices, this effort will continue

"hearing impaired interest" into "users of the Vibrant Soundbridge," which is the key goal for use in 2002 to help in this effort. We believe the favorable seminar attendance proves there into their practices. We have an ongoing audiology training program that we will continue to to the product and its clinical benefits begin to actively incorporate the Vibrant Soundbridge One of our key initiatives in 2002 is to have the audiology practices that have been introduced is strong interest from the hearing impaired in our product. This is the first step in turning

comfortable that there is a substantial self-pay market at our current price of around titteen of a consumer purchasing our product. This is consistent with our market research. We are partners overcome for the patient. Therefore, as a key initiative in 2002, we are aggressively thousand dollars (for the device and procedure), but this is a barrier we need to help our Initial feedback from the seminars indicates that price is the single biggest concern in terms





## 

Patented technologies. Proven partnership. Exciting new Direct Drive Simulator.





for moderate to severe sensorineural ZOOO Soundbridge hearing loss



Siemens Signia 8-channel DSP incorporated in the 404 Audio Processor

Completed key components of totally studies on implantable microphone implantable platform and in vivo

Upgraded packaging and housing for the Audio Processor

Audio Processor available in multiple





indications to include high frequency 2002 - FDA submission for expanded hearing loss New improved Audio Processor design with directional microphones

Direct Drive Simulator released to key customers

include dual microphones and further packaging upgrades. In the first half of IN LATE 2001, Symphonix introduced a newly packaged Audio Processor which is available in multiple colors and provides further cosmetic benefit to those patients who are concerned by the stigma of the hearing aid look. With more robust packaging and multiple colors, this new Audio Processor, the model 404, has been very favorably received by our patients. We also have in 2002, we will release our new Direct Drive Simulator which will be used as a sales tool to allow prospective patients to experience hearing with direct our R & D pipeline a plan for a next generation Audio Processor which will drive technology. We believe this tool will greatly enhance the patient's likelihood of purchasing our product. In addition to the significant upgrades we made to the semi-implantable platform, over the past year we made good progress on the totally implantable version of our product. All the key components of the totally implantable processor, titanium housing and leads, battery and the external programming Vibrant Soundbridge including the implantable microphone, mixed signal and charging components have all been performance tested and validated. With the completion of these key milestones along with our focus on the marketing of the semi-implantable Soundbridge, our investment in the totally implantable Soundbridge will be limited until management determines that conditions warrant increased investment.

BREAKING TECHNOLOGICAL ADVANCEMENTS. WE ARE WORKING HE SIEMENS PARTNERSHIP IS LEADING THE WAY FOR ER Siemens Audiologische

SIEMENS CONNEXX SOFTWARE, WHICH IS WELL ESTABLISHED WITH AUDIOLOGISTS WORLDWIDE, IS USED TO PROGRAM THE VIBRANT

SOUNDBRIDGE.

### SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

### FORM 10-K

(Ma	rk One)				
$\times$	ANNUAL REPORT PURSUANT TO SECURITIES EXCHANGE ACT OF				
	For the fiscal year ended: December 31, 2001				
	(	OR			
	TRANSITION REPORT PURSUANT SECURITIES EXCHANGE ACT OF :				
	For the transition period from to				
Commission File Number 000-23767					
SYMPHONIX DEVICES, INC. (Exact name of Registrant as specified in its charter)  Delaware  77-0376250					
	of incorporation or organization)	Identification Number)			
	2331 Zanker Road, San Jose, California (address of principal executive offices)	95131-1109 (zip code)			
	Registrant's telephone number, including area code: (408) 232-0710				
Securities registered pursuant to Section 12(b) of the Act:  None  Securities registered pursuant to Section 12(g) of the Act:					
	Common Stock, \$.001 par value	NASDAQ			
	To dispete the selection and contracts on the manifestation (1) 1	and Cited all manages managed to be Cited to Constitution			

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes [X] No [\_].

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K [X]

The aggregate market value of voting stock held by non-affiliates of the registrant as of March 7, 2002 was approximately \$19,900,000 based upon the last sales price reported for such date on the NASDAQ National Market System. For purposes of this disclosure, shares of Common Stock held by persons who hold more than 5% of the outstanding shares of Common Stock and shares held by officers and directors of the registrant, have been excluded in that such persons may be deemed to be affiliates. This determination is not necessarily conclusive.

At March 7, 2002, registrant had outstanding 35,597,490 shares of Common Stock.

### DOCUMENTS INCORPORATED BY REFERENCE

The information called for by Part III of this Form 10-K is incorporated by reference to the definitive proxy statement for the annual meeting of stockholders of Symphonix which will be filed no later than 120 days after December 31, 2001.

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### PARTI

This Annual Report on Form 10-K contains certain forward-looking statements within the meaning of Section 21E of the Securities Exchange Act of 1934, as amended, including statements that indicate what Symphonix "believes", "expects" and "anticipates" or similar expressions. These statements involve known and unknown risks, uncertainties and other factors which may cause actual results, performance or achievements of Symphonix to differ materially from those expressed or implied by such forward-looking statements. Such factors include, among others, the information contained under the captions Part I, Item 1, "Business," and Part II, Item 7 "Management's Discussion and Analysis of Financial Condition and Results of Operations" and "Additional Factors that May Affect Future Results" in this Annual Report. The reader is cautioned not to place undue reliance on these forward-looking statements, which reflect management's analysis only as of the date of this Annual Report. Symphonix undertakes no obligation to publicly release the results of any revision of these forward-looking statements. The reader is strongly urged to read the information set forth under the captions Part I, Item 1, "Business," and Part II, Item 7 "Management's Discussion and Analysis of Financial Condition and Results of Operations" for a more detailed description of these significant risks and uncertainties.

### ITEM 1. BUSINESS

### Overview

Symphonix Devices, Inc. develops, manufactures and markets the Vibrant® Soundbridge™, a proprietary line of hearing devices for the management of hearing impairment, a medical disorder that affects approximately 28 million people in the United States alone. The device consists of two components. One component is implanted in the middle ear and the other component is an external device worn behind the ear. Accordingly, we refer to this type of Vibrant Soundbridge as semi-implantable. Our Soundbridge products employ a middle ear implant technology designed to vibrate the small bones in the middle ear, enhancing the natural hearing process. Our Soundbridge products are currently being marketed in Europe in conjunction with our European distribution partner, Siemens Audiologische Technik GmbH of Erlangen, Germany, and have been approved by the U.S. Food and Drug Administration for use in the United States. We believe that our Soundbridge technology overcomes the inherent limitations of traditional hearing devices and represents a novel approach in the management of hearing loss.

In September 1996, we initiated clinical trials of the first-generation Vibrant Soundbridge in both the United States and Europe. In March 1998, we received authorization to market and sell the Vibrant Soundbridge in the European Union, and we received FDA approval in August 2000. Through a technology alliance with Siemens, we have developed our fourth generation Vibrant Soundbridge, based on an 8-channel digital signal processor. As of December 2001, over 750 patients have been implanted with the Vibrant Soundbridge in over 100 centers in both the United States and Europe.

Symphonix Devices, Inc. was incorporated in California in May 1994 and reincorporated in Delaware in December 1997. Our principal executive offices are located at 2331 Zanker Road, San Jose, California 95131-1109 and our telephone number at that address is (408) 232-0710. Our common stock is traded on The NASDAQ National Market and is quoted under the symbol "SMPX."

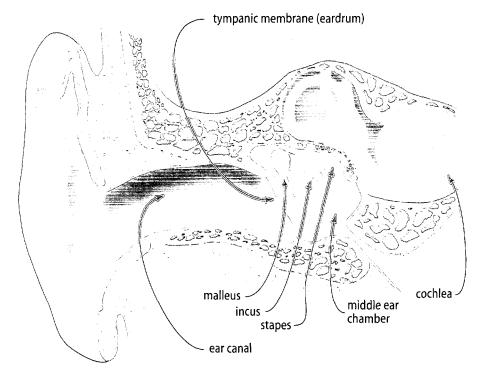
### How the Ear Works

The human ear consists of three regions: the outer ear, the middle ear and the inner ear. The outer ear consists of the external auricle and the ear canal. The ear canal is a passageway through which sound waves reach the middle ear. The outer ear is separated from the middle ear by the tympanic membrane, commonly referred to as the eardrum. The middle ear is a chamber that contains three tiny bones, the malleus, the incus, and the stapes that together are known as the ossicles. The ossicles form a chain from the tympanic membrane to the inner ear. The inner ear includes the cochlea, which is a fluid-filled structure that contains a large number of delicate sensory hair cells that are connected to the auditory nerve.

As sound enters the ear canal, it is slightly amplified by the natural resonant characteristics of the ear canal. The sound waves cause vibration of the tympanic membrane and are transmitted to the fluid filling the inner ear by the motion of the ossicles. The waves created in the fluid pass through the snail-shaped cochlea and stimulate the delicate sensory hair cells. These hair cells generate electrochemical signals that are detected by the auditory nerve and are then subsequently interpreted by the brain as sound.

Sound is distinguished by frequency and intensity. The frequency of sound is perceived as pitch and is measured in cycles per second, or Hertz. The normal human ear perceives sounds in the range of 20 to 18,000 Hz, although most components of human speech are generally in the range of 400 to 4,000 Hz. A more subtle aspect of frequency is that certain letters of the alphabet are spoken at a different frequency than others. For example, certain consonants such as "m," "n" and "g" and all vowels are spoken at relatively low frequencies while other consonants and sounds such as "t," "s," "f" and "sch" are spoken at higher frequencies. Accordingly, at a given volume, certain letters may be more audible than others.

The intensity of sound is perceived as loudness and is measured in decibels. The lowest level of intensity at which an individual perceives sound is known as the threshold of hearing. The range in decibels from a person's threshold of hearing to the level at which the person perceives sound to be uncomfortably loud is known as the dynamic range. Both the threshold of hearing and the dynamic range vary with the frequency of sound. An individual with normal hearing can comfortably hear sounds ranging in intensity from approximately 30 dB to 100 dB. When an individual's threshold of hearing is improved as a result of using a hearing instrument, the difference between the aided threshold level at a particular frequency and the unaided threshold level at that frequency is known as functional gain and is measured in decibels.



[Photograph of Anatomy of the Ear]

### Hearing Impairment

Hearing impairment can adversely affect quality of life and psychological well being. Hearing-impaired people often withdraw from discussions and other social interactions to avoid frustration and embarrassment from not being able to fully participate in and understand conversations. Difficulty in communicating effectively

can lead to negative emotions and attitudes, increased stress levels and reduced self-confidence, sociability and effectiveness in the workplace.

Approximately 28 million Americans are hearing-impaired. Hearing loss is one of the most prevalent chronic health conditions in the United States, affecting people of all ages, in all segments of the population, and across all socioeconomic levels. Hearing loss affects approximately 17 in 1,000 children under age 18. Incidence of hearing loss increases with age; approximately 314 in 1,000 people over age 65 have hearing loss. Hearing loss can be hereditary, or it can result from disease, trauma, or long-term exposure to damaging noise or medications. Hearing loss can vary from a mild but important loss of sensitivity, to a total loss of hearing.

Traditionally, statistics on hearing loss have shown seniors 65 years of age and older to be the most vulnerable age group with over 30% reporting hearing loss while approximately 10% in the 40 to 65 year age group acknowledge losses. This latter figure has increased as more and more baby boomers seek help for hearing-related issues.

Experts also agree that noise-induced hearing loss is to blame for most hearing loss for 40 and 50 year olds. Many of these baby boomers acknowledge that decibel-blasting rock and roll concerts in their youth have left lasting memories as well as permanent damage to the delicate hair cells in the inner ear which conduct electrochemical impulses to the brain where they are deciphered as sounds. The National Institute on Deafness and Communication Disorders (NIDCD) reports that 20,000,000 Americans are exposed to hazardous noise levels in dangerously noisy environments.

Hearing impairment can be characterized according to its physiological source. There are two general categories of hearing impairment, conductive and sensorineural, although sometimes a combination of the two may arise. Conductive hearing impairment results from diseases or disorders that limit the transmission of sound through the outer and/or middle ear. Conductive hearing impairment is often treated surgically with an implanted prosthesis to replace part or all of the ossicles. Symphonix believes that people with a conductive hearing loss represent a small portion of the total hearing-impaired population.

Symphonix believes that sensorineural hearing impairment, which occurs in the inner ear and/or neural pathways, accounts for the vast majority of hearing impairment. In patients with sensorineural hearing impairment, the external and middle ear function normally. The sound vibrations pass undisturbed through the eardrum and ossicles, and fluid waves are created in the cochlea. However, because some or many of the delicate sensory hair cells inside the cochlea have degenerated or been damaged, the inner ear cannot detect the full intensity and quality of the sound. Sensorineural hearing impairment typically occurs as a result of aging, exposure to loud noise over a protracted period of time, or heredity.

### **Existing Therapies**

The traditional approaches to managing sensorineural hearing impairment involve the use of hearing aids or cochlear implants. Hearing aids are commonly used to manage the mild to severe sensorineural hearing impaired population (approximately 24 million of the 28 million hearing-impaired people in the United States). Cochlear implants have been primarily used for the profound hearing-impaired segment of the market (less than 1 million people in the United States). However, both approaches have significant limitations in addressing their respective markets.

### Hearing Aids

Hearing aids are acoustic devices that amplify sound before it reaches the ear drum and vibrates the middle ear ossicles. The first electrically-enhanced hearing aid was invented about a hundred years ago and consisted of a microphone, amplifier, battery and speaker. More recently, hearing aid manufacturers have increased the sophistication of sound processing, often using digital technology to provide features such as programmability and multi-band compression, allowing different degrees of amplification at different frequencies. Hand-held

programmers have also been developed to compensate for the inability of hearing aids to adequately process sound in a variety of acoustic environments. In addition, as technology has enabled greater miniaturization, less obtrusive hearing aids have become available. Although there have been continued advancements in hearing aid technology, there are still many drawbacks:

Distorted sound quality. Obstructing the ear canal with either all or part of the hearing aid creates an effect known as occlusion which is an alteration of the ear canal's natural resonance that causes an unnatural and distorted sound.

Acoustic feedback. Feedback is a high pitched squeal which results when a speaker and microphone are placed in close proximity and the sound from the speaker is loud enough to be picked up by the microphone. As hearing aids have been manufactured in smaller configurations, the problem of feedback has become inherently greater due to the closer proximity of the speaker to the microphone.

Background noise. While hearing aid manufacturers continue to try and make their devices amplify speech only and not the "background noise", this continues to be a major complaint of hearing aid users.

Social stigma. Many hearing aid users and potential users perceive a strong social stigma related to wearing a hearing aid.

Discomfort. Hearing aids have been manufactured in smaller configurations in an attempt to address the perceived social stigma associated with wearing these devices. Since a tight fitting ear piece is required for optimal performance, the smaller versions of these devices must be placed deeper in the ear canal, which can cause substantial discomfort. Additionally, aging populations have increasing skin sensitivity which increases earmold discomfort in the ear canal.

Reliability. Hearing aids require frequent maintenance, in part due to their placement in the ear canal, where earwax can cause problems with the speaker or dampen the sound produced by the hearing aid. Hearing aids generally have to be replaced every three or four years, because of loss, damage or obsolescence. The need for periodic replacement increases the lifetime cost of wearing a hearing aid. Traditionally, most hearing aid users have paid for these devices directly.

Largely as a result of these problems, hearing aid manufacturers experienced product return rates of approximately 20% in 1999. In addition, approximately 16% of those who have purchased hearing aids report that they never wear their hearing aids. However, despite the inherent limitations of hearing aids, approximately 2.0 million new hearing aids were sold in the United States in 2001.

### Cochlear Implants

Cochlear implants were originally developed for people who have a profound hearing loss, approximately one million people in the United States alone. The cochlear implant is inserted into the inner ear in an invasive and non-reversible surgery that can destroy pre-surgery, unaided hearing (residual hearing). The implant electrically stimulates the auditory nerve through an electrode array that provides audible cues to the user which are not interpreted by the brain as normal sound. Users generally require intensive and extended counseling, speech therapy, and auditory training following surgery to be able to properly interpret these cues and to achieve benefit. Best results are achieved with adults whose hearing loss develops later in life and with children. Recently, some cochlear implants have been indicated for severe hearing loss. However, cochlear implants have been controversial both because of strong resistance from portions of the deaf community and because of the potential irreversible nature of the surgery in which the cochlea is invaded and residual hearing is destroyed. Accordingly, Symphonix does not believe that cochlear implants will achieve significant market penetration beyond their initial indication of profound hearing impairment. Symphonix estimates that the worldwide market for cochlear implant devices was approximately \$150 million in 2000.

### The Symphonix Solution

Symphonix has developed a proprietary semi-implantable Soundbridge for the management of moderate to severe hearing impairment. The Soundbridge families are based on our patented core technology, the Floating Mass Transducer<sup>TM</sup>, or FMT<sup>TM</sup>. The FMT is a tiny transducer that is designed to enhance hearing by precisely mimicking and amplifying the movements of the ossicles. While conventional approaches have indirectly driven the ossicles by amplifying sound in the ear canal to increase the vibrations of the tympanic membrane (ear drum), the FMT is attached directly to the ossicles and enhances the natural movement of these vibratory structures. This, in turn, enhances stimulation of the delicate sensory hair cells in the inner ear. With the Vibrant Soundbridge, the FMT receives electrical signals from an Audio Processor<sup>TM</sup>. The Audio Processor picks up sound from the environment and converts that sound into electrical signals which are then transmitted to an implant under the skin.

The Vibrant Soundbridge is implanted in a one and one-half hour surgery that can be performed on an outpatient basis utilizing techniques similar to those employed in routine otologic procedures. Based on clinical results, the Soundbridge has the following advantages over hearing aids and cochlear implants:

Does not significantly affect the patient's residual hearing. This means that the unaided hearing level after surgery is equivalent to the pre-surgery, unaided hearing level.

*Improves overall sound quality and clarity.* By leaving the ear canal unobstructed and the natural resonance undisturbed, a more natural sound quality over a broader range of frequencies is obtained.

*Improves fit and comfort.* No part of the Vibrant Soundbridge is inserted in the ear canal, resulting in increased comfort for users of the Vibrant Soundbridge.

*Reduces acoustic feedback.* Since the Vibrant Soundbridge mechanically drives the ossicles, it virtually eliminates acoustic feedback.

*Increases functional gain.* Users are able to experience greater output, or intensity, from their Soundbridge as compared to their hearing aid. As a result, their threshold level of hearing is improved.

Improves a patient's satisfaction and perceived benefit in both everyday and challenging listening situations. Patients are more satisfied with their hearing in many difficult listening environments, like those with background noise, as well as those in which they communicate directly with friends.

Reduces maintenance issues. Since no components of the Vibrant Soundbridge are in the ear canal, the reliability problems caused by wax and moisture are eliminated.

### Strategy

Our objective is to establish the Soundbridge technology as the standard of care worldwide for the management of mild to severe hearing impairment. The key elements of our strategy are:

Demonstrate improved functional performance and quality of life. We intend to promote the potential benefits of our products to the broad hearing-impaired population in order to reach the large number of people who are not being adequately treated for their medical disorder today. We believe that by demonstrating improvement in a patient's performance in a variety of listening environments, quality of life will increase and the Soundbridge will become a highly-differentiated approach to managing hearing impairment.

Develop broad awareness of Soundbridge technology within the otology, audiology and hearing-impaired communities. We are positioning the Soundbridge as a technologically-advanced surgical implant that addresses an unmet clinical need, creating a new option for the hearing-impaired. As its first stage of market development, Symphonix targeted otologists, a segment of the broader ENT population that specializes in ear surgery. Symphonix has focused on establishing partnerships with a core number of otologists in large metropolitan areas to offer the Soundbridge in their practices in order to establish a foundation prior to initiating marketing programs to drive patient flow. Now that this initial number of

otologists is set up, we have started the next stage of our market development. Symphonix is now extending its marketing efforts to audiologists—the health professionals who assess hearing problems and recommend hearing devices—and directly to those suffering hearing loss.

Support establishment of referring relationships. Generally, there are not pre-existing referring relationships between audiologists, the hearing healthcare professionals who dispense hearing aids and otologists, the ear surgeons who implant our device. Symphonix is focusing on establishing these referral networks and supporting them so that audiologists and otologists will work together to offer the Vibrant Soundbridge to patients and support patients who go forward with having the device implanted.

Leverage Symphonix's patented core technology. Symphonix intends to leverage its patented core FMT technology to develop next-generation Soundbridge devices. We intend to dedicate resources to continued research and development to further develop our core technology and to expand the medical indications for this technology. To further enhance system development, Symphonix intends to continue to leverage technology developed by Siemens, particularly in the area of signal processing, in accordance with the existing technology alliance between Siemens and Symphonix.

Protect and enhance Symphonix's proprietary position. Symphonix intends to continue to aggressively pursue protection for its proprietary technologies and products. Symphonix has 17 patents issued in the United States, 2 patents issued internationally and 5 patent families and 49 U.S. and international patents pending for a number of fundamental aspects of the FMT and related technologies.

### Existing Products and Products In Development Stage

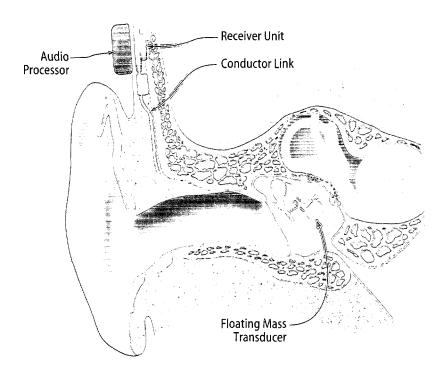
Symphonix has developed a proprietary semi-implantable Soundbridge, utilizing its core FMT technology to manage hearing impairment. We believe that our semi-implantable Soundbridge, the Vibrant Soundbridge, will enable us to address a significant portion of the moderate to severe hearing impairment market currently not satisfied with traditional hearing aid devices. The semi-implantable Soundbridge family utilizes the same implant, with differences in function being provided by modifications to the external Audio Processor, its software and/or programming platform. Utilization of a common implant will allow a user to upgrade the Audio Processor if a user's hearing changes over time, or as external processing technology continues to improve.

In addition, Symphonix has under development a totally implantable Soundbridge, which is being designed to be completely implanted under the skin with no external components. Although Symphonix has completed served milestones the development of the totally implantable Soundbridge, it has decided to limit further development of the totally implantable Soundbridge in order to manage its existing capital and focus its resources on marketing the semi-implantable Soundbridge family.

The following table describes the current portfolio of Soundbridges available, or under development, by Symphonix and their regulatory status:

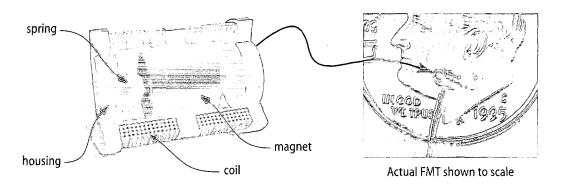
Soundbridge Family	Product Descriptions	Hearing Loss Addressed
FDA & EU APPROVED	<del> </del>	<del></del>
Semi-implantable (Vibrant Soundbridge)	Second generation semi-implantable hearing device with programmable dual channel analog	
	signal processing	Moderate to severe
	Third generation semi-implantable hearing	
	device, with programmable 3 channel digital	
	signal processing.	Moderate to severe
	Fourth generation semi-implantable hearing	
	device, with programmable 8 channel digital	
	signal processing, PC-based programming	Moderate to severe
CLINICAL TRIALS COMPLETED		
Semi-implantable (Vibrant Soundbridge)	Expanded inclusion criteria for the semi-	
	implantable Soundbridge includes people with	
	a mild to severe sensorineural hearing loss.	Mild to severe
DEVELOPMENT STAGE		
Totally Implantable	Designed to be completely implanted under the	
	skin with no external components, PC-based	
	programming	Mild to severe

The Vibrant Soundbridge has both external and implantable components. The external Audio Processor consists of (i) a microphone that picks up sound from the environment, (ii) sound processing circuitry that converts the sound to an electronic signal and modulates the signal to reduce potential noise interference from broad band electromagnetic fields, (iii) a small 1.5 volt battery that powers the device and (iv) a round magnet. The Audio Processor is placed on the head behind the ear and is held in place by magnetic attraction to an implanted receiver, the Vibrating Ossicular Prosthesis, or VORP<sup>TM</sup>. The Audio Processor is small enough to be concealed by most users' hair.



The VORP converts the electronic signal to a mechanical vibration of the ossicles in the middle ear. The VORP consists of (i) a receiver unit that receives the modulated electronic signal through the skin from the external Audio Processor and extracts the appropriate drive signal for the FMT, (ii) a conductor link that connects the implanted receiver unit to the FMT and (iii) the FMT, which is attached to the incus using a titanium clip. All of these components are insulated from body chemistry using well established implantable device materials used in pacemaker and implantable defibrillator systems.

The FMT is a tiny transducer, approximately 2mm in length, which comprises a permanent magnet suspended within a titanium housing. A coil surrounding the housing generates a small electromagnetic field based on the signal received from the VORP's receiver unit. The electromagnetic interaction of the magnet and the coil creates a mechanical vibration of the entire FMT. This vibration mimics and enhances the natural movement of the ossicles, which in turn generates enhanced stimulation of the sensory hair cells of the inner ear. A critical element of the proprietary FMT design is the proximity of the magnet to the electromagnetic field that causes the magnet to vibrate. By keeping the magnet and the coil close together, the FMT maximizes electromagnetic coupling while minimizing power consumption.



The surgical procedure for the implantation of the Vibrant Soundbridge involves techniques that are similar to those employed in other common otologic procedures. The internal receiver unit is implanted behind the ear, under the skin and muscle. The conductor link connecting the receiver unit to the FMT is placed through the excavated mastoid bone. These steps are similar to those required for the surgical placement of a cochlear implant receiver. In the middle ear, the FMT is attached to the ossicles in a manner similar to the way otologists have traditionally attached ossicular prostheses for management of conductive hearing loss to date, and consequently, training of the surgeons to perform the procedure has been straightforward. The procedure may be performed on an outpatient basis, and generally can be performed in about one and one-half hours. Approximately eight weeks following the surgery, an audiologist fits the Audio Processor with the appropriate sound processing settings. Symphonix's approved labeling from the FDA states that all results from the clinical trials are based on implantation in one ear. This will generally be the ear with the poorest unaided functional hearing. Based on clinical experience to-date, we believe that the surgical procedure can be reversed without damage to the patient's residual hearing.

### Existing Products—The Semi-Implantable Vibrant Soundbridge Family

The Vibrant P, Model 302 Soundbridge is designed to provide, through programming adjustments, a degree of customization to address the specific needs of a particular user's hearing loss, thereby permitting a broad range of hearing losses to be managed. At the time of fitting, the Audio Processor is connected to a hand-held programming unit that allows the audiologist to separately adjust the low and high frequency responses of the Audio Processor. This permits customization to the patient's needs in both the low and high frequency channels commensurate with their specific hearing loss characteristic.

We received approval to affix the CE mark to the Vibrant P, Model 302 Soundbridge in March 1998 and commenced selling activities in the European Union at that time. In the United States, the Premarket Approval was granted by the FDA in August 2000. The Vibrant P, Model 302 Soundbridge has superseded the first generation semi-implantable Soundbridge.

Symphonix has been implanting patients with mild to severe hearing losses in Europe since July 1998 when approval was given to affix the CE mark for the expanded criteria (mild to severe). In the U.S., patient enrollment in the clinical trial for this extension of inclusion criteria has been completed and is pending FDA approval which we expect in 2002.

The Vibrant D, Model 304 Soundbridge is similar to the Vibrant P, Model 302 Soundbridge, but is designed to permit an improved degree of customization to address the specific needs of a particular user's hearing loss, through digital signal processing. Fully automatic and independent sound processing in three separate frequency channels is provided. At the time of fitting, the Audio Processor is connected to a programming unit that allows the audiologist to adjust separately the low, middle and high frequency responses. This sophisticated system is capable of analyzing sound and automatically adjusting the Soundbridge's response.

Symphonix received approval to affix the CE mark to the Vibrant D, Model 304 Soundbridge in May 1999 and commenced selling activities in the European Union in June 1999. In the United States, the Premarket Approval was granted by the FDA in August 2000.

During 1999, Symphonix entered into an OEM Supply and Technology Agreement with Siemens. In accordance with this agreement, Siemens agreed to supply Symphonix its most advanced digital signal processing technology for use in Symphonix products. Additionally, Siemens agreed to license to Symphonix its state-of-the-art programming platform, known as the CONNEXX<sup>TM</sup> programming system.

Utilizing this new signal processing technology from Siemens, Symphonix has developed a fourth generation Audio Processor similar to the Vibrant D Soundbridge Model 304, but designed to permit an even greater degree of customization to address the specific needs of a particular user's hearing loss. This latest digital processing technology incorporates eight separate frequency channels that can be individually adjusted or adjusted in combinations of channels. At the time of fitting, the Audio Processor is connected to a programming unit that allows the audiologist to independently adjust each of the eight frequency response channels, providing more optimal tuning of the Soundbridge response to the patient's particular hearing loss. This sophisticated system, based on Siemens DSP technology, is capable of continuously analyzing sound and automatically adjusting the Soundbridge's response. This system incorporates new programming technology (CONNEXX) that will allow the audiologist to program the Audio Processor with greater flexibility and accuracy using a PC-based programmer. It is intended to provide automated algorithms for assisting the audiologist to more quickly and easily achieve the desired Soundbridge response.

Symphonix was authorized to begin marketing the Vibrant D, Model 404 Audio Processor in Europe in May of 2000 and commenced selling activities in the European Union shortly thereafter. In the United States, the Premarket Approval was granted by the FDA in January 2001.

### Product in Development Stage-Totally Implantable Soundbridge Family

Symphonix has under development versions of the Soundbridge for the management of mild to severe hearing impairment that are totally implantable with no external components. The essential function of the FMT for these products is the same as in the semi-implantable Soundbridge products. However, all the functions currently performed by the external Audio Processor have been designed to be performed by implanted components. Symphonix believes that the totally implantable Soundbridge, if successfully developed, will be applicable especially for people who are particularly physically active or who are concerned about aesthetics. In 2001, Symphonix completed several key milestones on the totally implantable Vibrant Soundbridge. However, in order to manage its existing capital it is focusing its resources on marketing the semi-implantable Vibrant Soundbridge; thus, Symphonix has decided to limit further development of the totally implantable Vibrant Soundbridge until management determines that conditions warrant increasing investment.

We cannot assure you that Symphonix's product development efforts with respect to the totally implantable Vibrant Soundbridge will be successfully completed, that Symphonix will in the future invest significant resources and capital to its totally implantable development efforts, or that products, if introduced, will achieve market acceptance.

### Sales and Marketing

### United States

In the United States, the primary market for Symphonix's products, the market is well-defined and easily identified. It consists of three constituents: 1) otologists, 2) audiologists and 3) those suffering from hearing loss. The first of the three constituents, otologists, are a segment of the ear, nose and throat, or ENT, group of doctors who specialize in ear surgery. Symphonix believes that there are approximately 400 otologists practicing in the U.S. Symphonix launched its product to the U.S. otology community at the annual American Academy of Otolaryngology conference in late 2000 and throughout 2001. Symphonix has initially targeted key otologists in large metropolitan areas and worked with them to offer the Soundbridge in their practices. Symphonix believes the response to the Soundbridge has been very favorable by the otology community both because the otologists see the benefits of the Soundbridge for those seeking an alternative to a hearing aid and because of the potential increase in patient flow to their practices. Symphonix is currently working with over 50 otologists. Because the surgical procedure for implanting the Soundbridge is similar to other procedures performed by otology centers, Symphonix has found that surgical training is minimal.

The second of the three constituents, audiologists, are the health professionals who assess hearing problems and recommend hearing devices. There are approximately 7,000 professional audiologists and an additional 3,000 dispensers of hearing aids. Those who suffer from hearing loss generally seek out an audiologist for testing for the type and severity of the hearing loss they have. The audiologist generally performs an audiogram on the patient to make the assessment of hearing loss. Once the audiogram is complete and the hearing loss defined, most often, the audiologist will recommend a solution for the patient, generally an acoustic hearing aid. Once they have purchased their hearing aid, most patients will need to see their audiologists three to four times a year for ongoing maintenance issues associated with acoustic hearing aids. Additionally, given that most hearing aids have a useful life of approximately three to four years, those currently with hearing aids will return to their audiologist to purchase new hearing aids about every three to four years. Symphonix is targeting audiologists as the key referral source for patient flow to the otologists. Symphonix believes audiologists will be compelled to refer patients to otologists for several reasons. They will see the benefit that the Soundbridge can bring to those patients in their practice who are looking for an alternative to a hearing aid; they believe that by being one of the first practices to offer this new implantable technology, they will better differentiate their practices from their competitors; they will have an ability to attract new patients who refuse to wear hearing aids; and finally, it will bring increased revenue and profitability to their practices. The audiologist will sell the external component of the Soundbridge much like they sell an acoustic hearing aid. The audiologist will program the device and be responsible for the ongoing management of the patient after the post operative follow up with the otologist is completed. Symphonix is initially targeting those audiologists in large metropolitan areas with large practices and are in close geographical proximity to an otologist who is offering the Soundbridge in their practice. Symphonix launched its outreach program to key audiologists in the second half of 2001. Symphonix expects this effort to continue to be an area of focus in 2002 and beyond.

To date, Symphonix believes that audiologists it has targeted and done outreach programs with are receptive to offering the Vibrant Soundbridge in their day to day practices. However, Symphonix believes that audiologists will only begin to actively offer the Vibrant Soundbridge in their day to day practice once they have had a small number of patients have the device implanted and post activation of the device are able to assess the patient's satisfaction with the device.

While Symphonix believes that some of its patient flow will come directly from otology practices, it believes that most of its patient flow will come from patients referred from an audiologist to an otologist. Generally, there are not pre-existing referral networks between audiologists and otologists. A main focus of Symphonix is to foster these referring relationships so that audiologists will refer patients to the otologist for the surgical implant of the device. Symphonix believes that these two constituents will see the benefits of a referring relationship as mutually beneficial and in the best interest of the patient. To date, Symphonix has seen a willingness of these two constituents to establish referring relationships.

The last of the three constituents is those who suffer from hearing loss. There are approximately 28 million people who suffer from hearing loss in the U.S. and the majority suffer from moderate to severe sensorineural hearing loss. There are just under 6 million hearing aid owners in the U.S. Because the Soundbridge is a new product and not widely known by those who suffer with hearing loss, outreach programs are needed for potential patients to be made aware of its benefits. Symphonix believes the best way to initially create awareness is through the audiologists, otologists, seminars, and advertising.

### Europe

In December 1999, Symphonix established a distribution partnership with Siemens covering most of the markets in Europe. As of January 1, 2001, Siemens assumed full distributorship for the European market. Symphonix believes this partnership will significantly enhance its presence, especially within the audiology community.

Symphonix's initial selling efforts in Europe have been targeted primarily at those ENT surgeons specializing in otology. Symphonix intends to continue to market its products to these specialists; however, with the Siemens agreement, Symphonix also plans to focus on referring physicians, audiologists, the general population of ENT physicians and potential patients in an attempt to increase the patient flow to the otology centers.

### Research and Development

Symphonix had 12 employees engaged in research and development, including regulatory and clinical affairs, as of December 31, 2001. Symphonix's research and development has focused on developing its patented core FMT technology, developing its family of Vibrant Soundbridges including a totally implantable version and conducting appropriate clinical testing. Symphonix expended approximately \$6.1 million, \$7.1 million and \$7.8 million for the years ended December 31, 2001, 2000, and 1999, respectively, on research and development. Due to limiting the development of the totally implantable Vibrant Soundbridge, Symphonix anticipates that it will reduce its level of expenditures in research and development in the coming year. Furthermore, the number of employees in research and development is expected to decrease during 2002 as major projects are completed.

### Manufacturing

Symphonix currently manufactures its products for commercial sales in the United States and Europe. The manufacture of Symphonix's Soundbridges is a complex operation involving a number of separate processes, components and assemblies. Each device is assembled and individually tested by Symphonix. The manufacturing process consists primarily of assembly of internally manufactured and purchased components and subassemblies, and certain processes are performed in an environmentally controlled area. After completion of the manufacturing and testing processes, a sub-contracted supplier sterilizes the implantable devices. Symphonix has no experience manufacturing its products in the volumes or with the yields that will be necessary for Symphonix to achieve significant commercial sales, and there can be no assurance that Symphonix can establish high volume manufacturing capacity or, if established, that Symphonix will be able to manufacture its products in high volumes with commercially acceptable yields. Symphonix will need to expend significant capital resources and develop manufacturing expertise to establish commercial-scale-manufacturing capabilities. Symphonix's inability to successfully manufacture or commercialize its Soundbridges in a timely manner could have a material adverse effect on Symphonix's business, financial condition and results of operations.

Raw materials, components and subassemblies for Symphonix's Soundbridges are purchased from various qualified suppliers and are subject to stringent quality specifications and inspections. Symphonix conducts quality audits of its key suppliers, several of whom are experienced in the supply of components to manufacturers of hearing devices and implantable medical devices, such as pacemakers, defibrillators and drug delivery pumps. A number of components and subassemblies, such as silicone, signal processing electronics and implant packaging is provided by single source suppliers. Certain components of the Vibrant Soundbridges are provided by sole source suppliers. None of Symphonix's suppliers is contractually obligated to continue to

supply Symphonix nor is Symphonix contractually obligated to buy from a particular supplier. For certain of these components and subassemblies, there are relatively few alternative sources of supply, and establishing additional or replacement suppliers for such components and subassemblies could not be accomplished quickly. In addition, if Symphonix wishes to significantly modify its manufacturing processes or change the supplier of a critical component, additional approvals will be required from the FDA before the change can be implemented. Because of the long lead time for some components and subassemblies that are currently available from a single source, a supplier's inability or failure to supply such components or subassemblies in a timely manner or Symphonix's decision to change suppliers could have a material adverse effect on Symphonix's business, financial condition and results of operations.

Symphonix's manufacturing facilities are subject to periodic inspection by regulatory authorities worldwide. In particular, its operations must undergo Quality System, or QS, regulation compliance inspections conducted by the FDA and corresponding state agencies as well as compliance inspections from our European notified body. Symphonix has been inspected by the Food and Drug Branch of the California Department of Health Services and a Device Manufacturing License has been issued to Symphonix. Symphonix has been FDA QS audited and certified and has also been inspected and recertified by our European notified body. Symphonix will be required to continually comply with the QS regulation requirements in order to produce products for sale in the United States and with applicable quality system standards and directives in order to produce products for sale in the EU. Any failure of Symphonix to comply with the QS regulation or applicable standards and directives may result in Symphonix being required to take corrective actions, such as modification of its policies and procedures. Pending such corrective actions, Symphonix could be unable to manufacture or ship any products, which could have a material adverse effect on Symphonix's business, financial condition and results of operations.

### Competition

The medical device industry and the acoustic hearing aid market are subject to intense competition in the United States and abroad. We believe our products will compete primarily with hearing aids. Principal manufacturers of acoustic hearing aids include Siemens Hearing Instruments, Inc., Starkey Laboratories Inc., GN ReSound Inc., Oticon, Inc., Widex Hearing Aid Co., Inc., Sonic Innovations and Phonak Inc. Our products may not be as reliable or effective as established hearing aid products. If our products are not perceived as high quality, reliable and effective alternatives to conventional hearing aids, we may not successfully compete with established hearing aid products. Our competitors may also develop technologies and products in the future that are more reliable and effective and less expensive than those being developed by us or that do not require surgery.

Several companies have active research and development and marketing programs related to direct drive devices, which employ a middle ear implant designed to vibrate the small bones in the middle ear for sensorineural hearing loss. This type of hearing loss is the most common form of hearing loss that affects the majority of the 28 million people in the United States who suffers from hearing loss. Otologics, LLC, has developed a semi-implantable direct drive device for sensorineural hearing loss called the Middle Ear Transducer (MET). This device has begun the FDA regulatory process and initiated multicenter clinical trials. Otologics has recently obtained the CE Mark in Europe that allows the company to market and sell its product in Europe. Symphonix believes that St. Croix has begun clinical trials in Europe and has recently received an IDE approval to begin clinical studies on its fully implantable pizo electric device for sensorineural hearing loss. Soundtec, Inc., has completed clinical trials in the United States on a hybrid implantable/ear canal based hearing aid and has recently obtained FDA approval to market their product in the U.S. In addition, some large medical device companies, some of which are currently marketing implantable medical devices, may develop programs in hearing management. Many of these companies have substantially greater financial, technical, manufacturing, marketing and other resources than we have. If we fail to compete effectively with any or all of these companies and products, we will not achieve profitability.

Symphonix believes that the primary competitive factors in the hearing management market will be the quality of the hearing enhancement, safety, whether surgery is required, reliability, endorsement by the surgeon and audiology communities, patient comfort, cosmetic result and price. Symphonix believes that it will be competitive with respect to these factors. Nonetheless, because Symphonix's products are either under development or in the very early stages of commercialization, the relative competitive position of Symphonix in the future is difficult to predict.

The medical device industry is characterized by rapid and significant technological change. Accordingly, Symphonix's success will depend also in part on its ability to respond quickly to medical and technological change and user preference through the development and introduction of new products that are of high quality and that address patient and surgeon requirements.

### Patents and Proprietary Technology

Symphonix holds 17 U.S. and 2 international patents and have a number of pending patent applications in the United States and internationally. These patents and applications cover the FMT—the key component of the Vibrant Soundbridge, invented by Symphonix Chief Technology Officer Geoff Ball—and the surgical method for installing the system. They also cover an implantable microphone—the technology used to produce microphones that can operate under the skin without external components.

Additionally, Symphonix has 5 patent families and 49 U.S. and international patents pending for technologies capable of treating all major types of hearing loss. Symphonix's success will depend in part on its ability to obtain patent protection for its products and processes, to preserve its trade secrets, and to operate without infringing or violating the proprietary rights of others.

The patent positions and trade secret provisions of medical device companies, including those of Symphonix, are uncertain and involve complex and evolving legal and factual questions. The coverage sought in a patent application either can be denied or significantly reduced before or after the patent is issued. Consequently, there can be no assurance that any patents from pending applications or from any future patent application will be issued, that the scope of the patent protection will exclude competitors or provide competitive advantages to Symphonix, that any of Symphonix's patents will be held valid if subsequently challenged or that others will not claim rights in or ownership of the patents and other proprietary rights held by Symphonix. Since patent applications are secret until patents are issued in the United States or corresponding applications are published in other countries, and since publication of discoveries in the scientific or patent literature often lags behind actual discoveries, Symphonix cannot be certain that it was the first to file patent applications for such inventions.

### Third-Party Reimbursement

Symphonix believes that the internal portion of its product will generally be purchased by hospitals and otology practices upon the recommendation of an otologic surgeon and the external portion will generally be purchased by audiologists. In the United States, hospitals, physicians and other health care providers that purchase medical devices generally rely on third-party payors, principally Medicare, Medicaid, private health insurance plans, health maintenance organizations and other sources of reimbursement for health care costs, to reimburse all or part of the cost of the procedure in which the medical device is being used. Such third-party payors have become increasingly sensitive to cost containment in recent years and place a high degree of scrutiny on coverage and payment decisions for new technologies and procedures.

Hearing aids, which do not involve surgery and, in certain cases, are exempt from the requirement for 510(k) approval, are generally not reimbursed, although a modest reimbursement is provided under certain insurance plans. Traditionally, hearing aid users have paid for these devices directly. For cochlear implants, however, which are technologically advanced and FDA-approved through the PMA process for the treatment of profound hearing impairment, a reimbursement is available for the device, the audiological testing, and the surgery. Similarly, reimbursement is available for ossicular replacement prostheses that are FDA-cleared for the treatment of conductive/mixed hearing loss.

Symphonix is pursuing reimbursement for the Soundbridge, based primarily on surgeon endorsement as a medical necessity. Other factors include demonstrated performance of the Soundbridge and quality of life improvement. Quality of life issues were included in Symphonix's clinical trial to provide data in support of this reimbursement strategy. Recently, Symphonix has had a small number of cases covered by third-party payors. However, Symphonix may not obtain wide spread reimbursement for its product from private insurers.

Certain third-party payors are moving toward a managed care system in which they contract to provide comprehensive health care for a fixed cost per person. The fixed cost per person established by these third-party payors may be independent of the hospital's cost incurred for the specific case and the specific devices used. Medicare and other third-party payors are increasingly scrutinizing whether to cover new products and the level of reimbursement for covered products. Failure by physicians, hospitals and other potential users of Symphonix's products to obtain sufficient reimbursement from third-party payors for the procedures in which Symphonix's products are intended to be used could have a material adverse effect on Symphonix's business, financial condition and results of operations.

Third-party payors that do not use prospectively fixed payments increasingly use other cost-containment processes or require various outcomes data that may pose administrative hurdles to the use of Symphonix's products. In addition, third-party payors may deny reimbursement if they determine that the device used in a procedure is unnecessary, inappropriate, experimental, used for a non-approved indication or is not cost-effective. Potential purchasers must determine that the clinical benefits of Symphonix's products justify the additional cost or the additional effort required to obtain prior authorization or coverage and the uncertainty of actually obtaining such authorization or coverage.

Market acceptance of Symphonix's products and products currently under development in international markets is dependent, in part, upon the availability of reimbursement within prevailing health care payment systems. Reimbursement and health care payment systems in international markets vary significantly by country, and include both government sponsored health care and private insurance. Symphonix believes that in Europe, the primary source of funding for products such as Symphonix's products is the various government sponsored healthcare programs. Siemens has filed on behalf of Symphonix reimbursement dossiers for the Vibrant Soundbridge in France and in a number of provinces in Germany. However, requirements for the granting of reimbursement are not clearly specified and failure to receive international reimbursement approvals could have a material adverse effect on market acceptance of Symphonix's products in the EU as well as in international markets in which such approvals are sought.

Symphonix believes that in the future reimbursement will be subject to increased restrictions both in the United States and in international markets. Symphonix believes that the overall escalating cost of medical products and services will continue to lead to increased pressures on the health care industry, both foreign and domestic, to reduce the cost of products and services, including Symphonix's products and products currently under development. The unavailability of third-party payor coverage or the inadequacy of reimbursement could have a material adverse effect on Symphonix's business, financial condition and results of operations.

### Product Liability

Symphonix's business involves the inherent risk of product liability claims. Symphonix maintains limited product liability insurance at coverage levels which Symphonix believes to be commercially reasonable and adequate given Symphonix's current operations. However, there can be no assurance that such insurance will continue to be available on commercially reasonable terms, or at all, or that such insurance will be adequate to cover liabilities that may arise. Any claims that are brought against Symphonix could, if successful, have an adverse effect on Symphonix's business, financial condition and results of operations.

### Employees

At December 31, 2001, Symphonix had 49 employees. Of these employees, 12 were in research and development, including regulatory and clinical affairs, 10 were in manufacturing and quality assurance and 27 were in administration, sales and marketing. None of Symphonix's employees are covered by a collective bargaining agreement and Symphonix believes that it maintains good relations with its employees.

### Scientific Advisory Board

Symphonix established 2 scientific advisory boards. The Audiology Advisory Board consists of six leading audiologists. This board brings an audiological perspective to clinical protocol issues, audiological testing, interpretation of results, marketing strategy and consumer issues. The Medical Advisory Board consists of five otologists of worldwide prominence. These physicians review patient-related issues, provide feedback on product designs and assist with product and protocol development. In addition to periodic meetings of the boards, members of the boards are available on an individual basis to consult with Symphonix. Symphonix also uses its clinical investigator surgeons as advisors and from time to time holds investigator meetings to discuss results, surgical techniques and product enhancements.

### ITEM 2. PROPERTIES

Symphonix's principal administrative, manufacturing and research and development facility occupies approximately 30,500 square feet in San Jose, California, pursuant to a lease that expires in December 2002.

### ITEM 3. LEGAL PROCEEDINGS

Symphonix has filed a complaint against Soundtec, Inc., the Central Ear Research Institute (CERI) and three senior Soundtec executives in late 2001 alleging actions that include misappropriation of trade secrets, breach of contract and inducing breach of contract. Central to the complaint is Symphonix's contention that Soundtec and its three executives utilized Symphonix's confidential, proprietary and trade secret information to develop and market the Direct System™, Soundtec's implantable middle ear hearing device. Prior to their tenure at Soundtec, the three executives named in the complaint were employed by CERI, which, in December 1994, entered into an agreement to undertake a research and development project with Symphonix on the development of an implantable hearing device. The agreement permanently transferred exclusive rights to Symphonix for all technology developed during the research period. It further required that CERI disclose and permanently transfer rights to Symphonix for all improvements invented, development or otherwise acquired by CERI for five years after termination of the agreement. Two of the named executives in the complaint executed this agreement on CERI's behalf. Soundtec was founded in March 1997, five months after CERI terminated its agreement with Symphonix. Among other requests, Symphonix is seeking to restrain Soundtec from selling its Direct System device for a period of two years and to collect related damages.

### ITEM 4. SUBMISSION OF MATTERS TO A VOTE OF SECURITY HOLDERS

None.

### PART II

### ITEM 5. MARKET FOR REGISTRANT'S COMMON EQUITY AND RELATED STOCKHOLDER MATTERS

Symphonix's common stock is traded on the NASDAQ National Market under the symbol "SMPX". The following table sets forth, for the periods indicated, the range of the low and high sales prices for Symphonix's common stock as reported on the NASDAQ National Market.

	High	Low
Fiscal 2000:		
First Quarter	\$6.44	\$3.25
Second Quarter	\$6.50	\$2.88
Third Quarter	\$9.94	\$3.63
Fourth Quarter	\$5.25	\$1.25
Fiscal 2001:		
First Quarter	\$3.75	\$1.03
Second Quarter	\$2.25	\$1.06
Third Quarter	\$1.30	\$0.36
Fourth Quarter	\$0.46	\$0.24

As of March 7, 2002, there were approximately 4,000 holders of record of the common stock. On March 7, 2002, the last reported sale price on the NASDAQ National Market for the common stock was \$0.56.

Symphonix has not declared or paid any cash dividends on its common stock. Symphonix presently intends to retain earnings, if any, for use in its business and therefore does not anticipate paying cash dividends in the foreseeable future.

### ITEM 6. SELECTED FINANCIAL DATA

### SELECTED CONSOLIDATED FINANCIAL DATA (In thousands, except per share amounts)

The consolidated statement of operations data for each of the three years in the period ended December 31, 2001 and the consolidated balance sheet data at December 31, 2001 and 2000 are derived from the audited consolidated financial statements included in this report. The consolidated statement of operations data for each of the two years in the period ended December 31, 1998 and the consolidated balance sheet data at December 31, 1999, 1998 and 1997 are derived from audited financial statements not included in this report. Our historical results are not necessarily indicative of results to be expected for future periods. The consolidated financial data set forth below should be read in conjunction with the accompanying consolidated financial statements of Symphonix and related notes thereto, and Management's Discussion and Analysis of Financial Condition and Results of Operations.

	Year Ended December 31,				
	2001	2000	1999	1998	1997
Consolidated Statements of Operations Data: Revenues	\$ 2,020	\$ 1,247	\$ 331	\$ 597	\$ —
Costs and expenses:  Costs of goods sold	4,280 6,104 9,158	3,094 7,119 8,654	4,078 7,848 5,847	1,663 8,322 5,633	
Total costs and expenses	19,542	18,867	17,773	15,618	8,466
Operating loss	(17,522) 793	(17,620) 463	(17,442) 763	(15,021) 1,375	(8,466) 475
Net loss	\$(16,729)	\$(17,157)	\$(16,679)	\$(13,646)	\$(7,991)
Basic and diluted net loss per common share	\$ (0.60)	\$ (1.18)	\$ (1.35)	\$ (1.24)	\$ (3.10)
Shares used in computing basic and diluted net loss per common share	27,798	14,594	12,393	10,987	2,579
	December 31,				
	2001	2000	1999	1998	1997
Consolidated Balance Sheet Data:  Total assets  Working capital  Long-term debt and capital lease obligations  Stockholders' equity	\$ 15,155 \$ 9,033 \$ 500 \$ 9,288	\$ 34,030 \$ 25,878 \$ 1,000 \$ 25,519	\$ 17,934 \$ 11,256 \$ 1,508 \$ 10,655	\$ 28,695 \$ 21,791 \$ 2,098 \$ 23,875	\$13,141 \$ 9,554 \$ 2,325 \$ 8,463

### ITEM 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

### Overview

Statements in this Management's Discussion and Analysis of Financial Condition and Results of Operations which express that Symphonix "believes", "anticipates" or "plans to" as well as other statements which are not historical fact, are forward looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. Actual events or results may differ materially as a result of the risks and uncertainties described herein and elsewhere including, in particular, those factors described under "Business" and "Additional Factors That Might Affect Future Results."

Symphonix has developed a family of proprietary implantable Soundbridges for the management of mild to severe hearing impairment. Symphonix's family of Vibrant Soundbridges is based on its patented core FMT technology. Late in 2000, Symphonix received approval from the Food and Drug Administration to commercially market its product in the United States. Subsequent to FDA approval, the product was successfully launched to the otology community. Otologists are ear surgeons within the ear, nose and throat group of doctors.

Symphonix has established a United States sales and marketing organization which, as of December 31, 2001, was comprised of nineteen (19) sales, marketing and clinical support personnel. Symphonix has initiated marketing efforts focused on otologists, audiologists—the health professionals who assess hearing problems and recommend hearing devices—and directly to those suffering hearing loss.

Symphonix received the authorization to affix the CE Mark to the first generation Vibrant Soundbridge and the second generation Vibrant P, Model 302 Soundbridge in March 1998. Authorization to affix the CE Mark to the Soundbridge and the Vibrant D, Model 304 Soundbridge was received in July 1998 and in May 1999, respectively. Symphonix began selling activities for the Vibrant P, Model 302 Soundbridge and for the Vibrant D, Model 304 Soundbridge in the European Union in March 1998 and in June 1999, respectively. In August 2000, Symphonix received FDA approval for its premarket approval application, or PMA, for the Vibrant P, Model 302 and Vibrant D, Model 304 Soundbridges. In October 2000, Symphonix received its device license for the Vibrant Soundbridge from Health Canada. Symphonix was authorized to begin marketing the Vibrant D, Model 404 in Europe in May 2000 and received Premarket Approval by the FDA in January 2001.

In December 1999, Symphonix established a distribution partnership with Siemens Audiologische Technik GmbH covering most of the markets in Europe. As of January 1, 2001, Siemens was granted full distributorship of the European market. Symphonix believes this partnership will significantly enhance its presence, especially within the audiology community.

Symphonix's initial selling efforts in Europe have been targeted primarily at those ENT surgeons specializing in otology. Symphonix intends to continue to market its products to these specialists; however, with the Siemens agreement, it also plans to focus on referring physicians, audiologists, the general population of ENT physicians and potential patients in an attempt to increase the patient flow to the otology centers.

On August 31, 2000, the FDA approved the Vibrant Soundbridge for commercial distribution in the United States for adults with a moderate to severe hearing loss. Symphonix has recently completed a clinical trial for adults with a mild hearing loss. Symphonix has filed a PMA supplement to expand its application for adults with a mild to severe sensorineural hearing loss and expects approval of this supplement in 2002.

Symphonix has a limited operating history. Through December 31, 2001 Symphonix had not generated significant revenue from product sales. Symphonix expects to incur substantial losses through at least 2002. To date, Symphonix's principal sources of funding have been net proceeds from its initial public offering completed in February 1998, private equity financings including investments by Siemens, an equipment lease facility and bank borrowings.

### Results of Operations

Revenues. Revenues of \$2.0 million, \$1.2 million and \$0.3 million were recorded in the years ended December 31, 2001, 2000 and 1999, respectively, for sales of the Vibrant Soundbridge in North America, Europe and Latin America. The increase in revenues for the year ended December 31, 2001 compared to the same periods in 2000 and 1999 is due to increased unit sales in the U.S. resulting from increased investments in sales and marketing activities. Included in revenue for 2001, 2000 and 1999 is \$0.4 million, \$0.4 million and zero, respectively, representing the amortization of \$1,885,000 which was the difference between the purchase price and the fair market value of Symphonix's common stock purchased by Siemens in accordance with a marketing and distribution agreement. The deferred revenue is being amortized on a straight line basis over the five year life of the agreement.

Costs of Goods Sold. Costs of goods sold were \$4.3 million, \$3.1 million and \$4.1 million in the years ended December 31, 2001, 2000 and 1999, respectively, and represent the direct cost of the products sold as well as warranty provisions and production variances. Warranty expense is computed based on the number of audio processor units outstanding. In 1999, when these units began shipping, Symphonix reserved approximately 65% of the units outstanding, representing \$320,000 in warranty provision less \$72,000 in warranty cost charged against the provision. In 2000, Symphonix reserved approximately 58% of units outstanding, representing \$1,248,000 in warranty provision less \$377,000 in warranty cost charged against the provision. In 2001, Symphonix charged \$279,000 in warranty costs against the provision. At December 31, 2001 the remaining provision of \$840,000 represents approximately 47% of units outstanding. The decrease in percentage of units outstanding reserved for the year ended December 31, 2001 is due to fewer units covered by the warranty as a percentage of units outstanding.

Research and Development Expenses. Research and development expenses were \$6.1 million, \$7.1 million, and \$7.8 million in the years ended December 31, 2001, 2000, and 1999, respectively. Research and development expenses consist primarily of personnel costs, professional services, materials, supplies and equipment in support of product development, clinical trials, regulatory submissions and the preparation and filing of patent applications. Research and development expenses decreased from 1999 to 2000 in part due to the PMA approval from the FDA. Research and development expenses decreased from 2000 to 2001 due to the completion of a number of key research and development milestones and subsequent reduction in consulting and project costs.

Selling, General and Administrative Expenses. Selling, general and administrative expenses were \$9.2 million, \$8.7 million, and \$5.8 million in the years ended December 31, 2001, 2000, and 1999, respectively. Selling, general and administrative expenses consist primarily of personnel, marketing, legal and consulting costs. Expenses increased from 1999 to 2000 due to the development of the U.S. marketing and selling organization in conjunction with the U.S. product launch. Expenses increased from 2000 to 2001 due to further development of the U.S. marketing and selling organization.

In November 2000, Symphonix approved plans to restructure its operations in order to accelerate the Marketing and Distribution Agreement signed with Siemens in December 1999. In the fourth quarter of 2000, Symphonix recorded a charge of \$509,000 in connection with the restructuring. The following table sets forth certain details associated with the net reorganization charges as of December 31, 2001 (in thousands of dollars):

	Restructuring Accrual at Dec. 31, 2000	Cash Payments	Adjustments	Restructuring Accrual at Dec. 31, 2001
Severance and benefits	\$262	\$(165)	\$ (97)	\$
Facility charges	111	(45)	(66)	
Other	136	(136)		<del></del>
	<u>\$509</u>	\$ 346	\$(163)	<u>\$ —</u>

Severance and benefits represent the reduction of 10 sales and marketing employees in Europe. Write-off of assets consisted primarily of computer equipment, furniture, and fixtures. These assets were written off because they were excess and could not be used in any other Symphonix facility since the cost of moving the assets would be greater than the net book value of the assets. Facility charges include early termination costs associated with the closing of the international sales office. Cash payments relating to these accruals were paid in the first half of 2001. In the three month periods ended March 31, 2001 and September 30, 2001, Symphonix reversed \$82,000 and \$81,000, respectively, of excess reorganization charges related to severance and facility charges which are included in selling, general and administrative expenses in the statement of operations.

Deferred compensation of \$2.3 million was recorded in 1997, representing the difference between the exercise prices of certain options granted and the deemed fair value of Symphonix's common stock on the grant dates. Deferred compensation expense of \$34,000, \$295,000, and \$517,000 attributed to such options was amortized during the years ended December 31, 2001, 2000, and 1999, respectively. During 2001, 2000 and 1999, Symphonix reversed zero, \$411,000 and \$260,000, respectively, of unrecognized deferred compensation relating to employees that have terminated employment with Symphonix.

Interest Income, net. Interest income, net was \$793,000, \$463,000, and \$763,000 in the years ended December 31, 2001, 2000, and 1999, respectively. The increase from 2000 to 2001 was due to an increase in cash associated with a private placement in 2000. The decrease from 1999 to 2000 was due to the overall lower cash balances during the period.

Income Taxes. To date, Symphonix has not incurred any U.S. income tax obligations. At December 31, 2001, Symphonix had net operating loss carryforwards of approximately \$74.9 million for federal and \$39.0 million for state income tax purposes, which will expire at various dates through 2021 and 2011, respectively, if not utilized. The principal differences between losses for financial and tax reporting purposes are the result of the capitalization of research and development and start-up expenses for tax purposes. United States and state tax laws contain provisions that may limit the net operating loss carryforwards that can be used in any given year, should certain changes in the beneficial ownership of Symphonix's outstanding common stock occur. Such events could limit the future utilization of Symphonix's net operating loss carryforwards.

### Liquidity and Capital Resources

Since its inception, Symphonix has funded its operations and its capital expenditures from proceeds of its initial public offering completed in February 1998 totaling \$28.4 million, net of issuance costs, from the private sale of equity securities totaling \$62.5 million, from an equipment lease financing totaling \$1.3 million and from bank borrowings totaling \$2.0 million, net. Included in the \$62.5 million private sale of equity securities was \$5.0 million to Siemens, which is the second component of the \$10.0 million invested by Siemens, and \$26.0 million in a private placement in 2000. At December 31, 2001, Symphonix had \$9.0 million in working capital, and its primary source of liquidity was \$12.1 million in cash and cash equivalents and short-term investments.

Capital expenditures, related primarily to Symphonix's research and development and manufacturing activities, were \$749,000, \$608,000, and \$220,000 in the years ended December 31, 2001, 2000, and 1999 respectively. The increased capital expenditures in 2000 from 1999, and in 2001 from 2000, relate primarily to the purchase of test/production equipment. At December 31, 2001, Symphonix did not have any material commitments for capital expenditures.

In October 1997, Symphonix entered into a lease agreement for a new facility for a five year term commencing January 1998. During the quarter ended March 31, 1998 Symphonix relocated its research and development and administrative functions to the new facility. Symphonix completed the relocation of its manufacturing activities to the new facility in April 1998. Through December 31, 2001, Symphonix has made approximately \$2.5 million in capital expenditures, primarily attributable to leasehold improvements and furniture and fixtures related to the new facility.

Symphonix has a loan agreement with a bank providing for borrowings of up to \$2.0 million and for the issuance of letters of credit up to \$250,000. At December 31, 2001, Symphonix had borrowings outstanding of \$1.0 million, outstanding letters of credit in the amount of \$174,000 and no amounts available for future borrowings under the loan agreement. Borrowings under the loan agreement are repayable over four years commencing in January 2000.

Symphonix used \$16.3 million in cash for operations in 2001, which was a slight increase from \$15.8 million in 2000. The primary use of cash was to fund operating losses during the year.

Since Symphonix's formation in May 1994 through December 2001, Symphonix has generated an accumulated deficit of approximately \$82.7 million. Symphonix expects negative cash flow from operations to continue through 2002, as Symphonix continues the development of the Vibrant Soundbridge system, conducts clinical trials required for FDA clearance of new products and continues its marketing and sales capabilities and administrative infrastructure. Beginning in late 2001 and continuing into 2002, Symphonix has instituted a series of actions to rationalize its operations to provide lower operating costs while increasing efficiencies. If revenue growth does not match projections, Symphonix will take actions necessary to reduce fixed costs commensurate with the level of revenue achieved. As a result of these actions, Symphonix currently estimates that its capital resources will be sufficient to meet its short-term capital needs through at least 2002.

Although Symphonix has reduced its spending on research and development, preclinical and clinical testing, capital expenditures and the manufacturing, marketing and sale of its products during 2001, these expenditures could increase in the future. The timing and amount of spending of such capital resources cannot be accurately predicted and will depend on several factors, including: market acceptance and demand for Symphonix's products in the United States and internationally, the availability of third party reimbursement, the progress of Symphonix's research and development efforts and preclinical and clinical activities, competing technological and market developments, the time and costs of obtaining regulatory approvals, the time and costs involved in filing, prosecuting and enforcing patent claims, the progress and cost of commercialization of products currently under development, and other factors not within Symphonix's control. While Symphonix believes that its existing capital will be sufficient to fund its operations and its capital investments through 2002, Symphonix may require additional financing beyond that time and there can be no assurance that financing will be available. In addition, there can be no assurance that such additional financing will be available on a timely basis on terms acceptable to Symphonix, or at all, or that such financing will not be dilutive to stockholders. If adequate funds are not available, Symphonix could be required to delay development or commercialization of certain of its products, license to third parties the rights to commercialize certain products or technologies that Symphonix would otherwise seek to commercialize for itself, or reduce the marketing, customer support or other resources devoted to certain of its products, any of which could have a material adverse effect on Symphonix's business, financial condition and results of operations.

### Critical Accounting Policies

Symphonix's discussion and analysis of its financial condition and results of operations are based upon the consolidated financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States of America. The preparation of these financial statements requires Symphonix to make estimates and judgements that affect the reported amounts of assets, liabilities, revenues, and expenses, and related contingent liabilities. On an on going basis Symphonix evaluates its estimates, including those related to revenues, collectibility of receivables, inventories, investments, income taxes, contingencies and litigation. Symphonix bases its estimates on historical experience and on various other assumptions that are believed to be reasonable under the circumstances. Actual results may differ from these estimates under different assumptions or conditions.

Symphonix's critical accounting policies are as follows:

### Revenue Recognition

Symphonix recognizes revenue from product sales upon shipment to the customer against a valid purchase order, provided no significant obligations remain and collection of the receivables is probable. Upon shipment, Symphonix provides for estimated product returns and estimated costs that may be incurred for product warranties.

### **Estimating Expenses**

On an ongoing basis, Symphonix evaluates its estimates for expenses including bonus and commissions related to our sales force, collectibility of receivables, inventory reserves, impairment of investments, valuation allowance for deferred income taxes, warranty provisions and other various expenses. Symphonix bases its estimates on historical experience and on various other assumptions that are believed to be reasonable under the circumstances. Actual results may differ from those estimates under different assumptions and conditions.

### **Recent Accounting Pronouncements**

In July 2001, the Financial Accounting and Standards Board ("FASB") issued Statements of Financial Accounting Standards No. 141 ("SFAS 141"), "Business Combinations," and No. 142 ("SFAS 142"), "Goodwill and Other Intangible Assets." SFAS 141 requires that all business combinations initiated after June 30, 2001 be accounted for under a single method—the purchase method. Use of the pooling-of-interests method is no longer permitted. SFAS 142 requires that goodwill no longer be amortized to earnings, but instead be reviewed for impairment upon initial adoption of the Statement and on an annual basis going forward. The amortization of goodwill will cease upon adoption of SFAS 142. The provisions of SFAS 142 will be effective for fiscal years beginning after December 15, 2001. Symphonix believes that SFAS 142 will not have a material effect on the financial position or results of operations of Symphonix.

In October 2001, the FASB issued Statement of Financial Accounting Standards No. 144 ("SFAS 144"), "Accounting for the Impairment or Disposal of Long-Lived Assets," which is effective for fiscal years beginning after December 15, 2001 and interim periods within those fiscal periods. SFAS 144 supersedes FASB Statement No. 121 and APB Opinion No. 30, however, it retains the requirement of Opinion No. 30 to report discontinued operations separately from continuing operations and extends that reporting to a component of an entity that either has been disposed of (by sale, by abandonment, or in a distribution to owners) or is classified as held for sale. SFAS 144 addresses financial accounting and reporting for the impairment of certain long-lived assets and for long-lived assets to be disposed of. Symphonix believes that SFAS 144 will not have a material impact on the financial position or results of operations of Symphonix.

### ADDITIONAL FACTORS THAT MIGHT AFFECT FUTURE RESULTS

### SYMPHONIX MAY BE DELISTED ON THE NASDAQ NATIONAL MARKET.

To maintain a listing on the NASDAQ National Market, a company must maintain a minimum bid price per share of \$1.00 as required under Marketplace Rules 4450(a)(2) and 4450(a)(5), respectively. Our common stock has traded below \$1.00 since August 2, 2001. On February 14, 2002 we received a letter from the NASDAQ National Market informing us that we have until May 15, 2002, to regain compliance. Symphonix may regain compliance if, at anytime before May 15, 2002, the bid price of Symphonix's common stock closes at \$1.00 per share or more for a minimum of 10 consecutive trading days. If Symphonix's common stock is delisted from the NASDAQ National Market, Symphonix will list its securities on the NASDAQ SmallCap Market ("SmallCap Market"). Like the NASDAQ's National Market, the NASDAQ SmallCap Market is a NASDAQ regulated exchange.

A delisting from the NASDAQ National Market could impair our ability to raise additional working capital. If we are able to raise additional capital, the terms may not be favorable and your investment may be diluted. A delisting may impair the liquidity of our common stock and may make it difficult for you to sell your shares, and you may lose some or all of your investment.

### WE HAVE A HISTORY OF LOSSES AND NEGATIVE CASH FLOWS, AND WE MAY NEVER BE PROFITABLE.

We have incurred losses every year since we began operations in 1994. At December 31, 2001, we had an accumulated deficit of \$82.7 million. This deficit resulted primarily from expenses we incurred from dedicating substantially all of our resources to research and development, clinical trials and establishment of a U.S. sales and marketing organization. The Vibrant P, Model 302 and Vibrant D, Model 304 Soundbridges became available for sale in the European Union in 1998 and in the United States and Canada in 2000. Symphonix was authorized to begin marketing the Vibrant D, Model 404 in Europe in May 2000 and received Premarket Approval by the FDA in January 2001. However, we have not generated significant revenues from product sales to date. We may never realize significant product revenues. Even if we do achieve significant product revenues, we may never be profitable. We expect our operating losses to continue at least through the year 2002 as we continue to, among other things:

- · invest in sales and marketing capabilities;
- · continue research and development activities;
- · conduct clinical trials in support of regulatory approvals; and
- establish commercial-scale manufacturing capabilities.

### SINCE THIRD-PARTY REIMBURSEMENT IS NOT WIDELY AVAILABLE FOR PROCEDURES USING OUR SOUNDBRIDGE PRODUCTS, OUR PRODUCTS MAY NOT ACHIEVE MARKET ACCEPTANCE.

In the United States and abroad, patients generally rely on third-party payors, principally Medicare, Medicaid, private health insurance plans, health maintenance organizations and other sources of reimbursement, to pay health care expenses, including reimbursement of all or part of the cost of the procedure in which our medical device is being used. These third-party payors are increasingly attempting to limit both the coverage and the level of reimbursement of procedures involving new devices. Currently, we have had only a small number of cases covered by third-party payors. If third-party payors do not establish adequate levels of reimbursement for procedures using our products, we may not achieve market acceptance.

### IF OUR SOUNDBRIDGE PRODUCTS DO NOT ACHIEVE MARKET ACCEPTANCE, OUR BUSINESS MAY FAIL.

We have sold the semi-implantable Vibrant Soundbridge in Europe since 1998 and in the United States since 2000 and, as of March 7, 2002, have sold approximately 800 units. This product has not yet achieved market acceptance and may never achieve market acceptance. Market acceptance of our current and future Soundbridge products will depend upon their acceptance by the medical community and patients as safe, effective, and cost-effective compared to other devices. Our Soundbridge products may not be preferable alternatives to existing or future products, some of which, such as the acoustic hearing aid, do not require surgery. Patient acceptance of our Soundbridge products will depend in part upon physician, audiologist and surgeon recommendations as well as other factors, including the effectiveness, safety, reliability and invasiveness of the procedure as compared to established approaches. Prior to undergoing surgery for the implantation of our Soundbridge, a patient may speak with a number of medical professionals, including the patient's primary care physician, an audiologist, an ear, nose and throat specialist, as well as surgeons who specialize in ear surgery. The failure by any of these medical professionals to favorably recommend our products and the surgery required to implant the Soundbridge could limit the number of potential patients who are introduced to an ear surgeon as

candidates for our Soundbridge products. If our Soundbridge products do not achieve market acceptance, our business may fail.

### IF WE FAIL TO SUCCESSFULLY DEVELOP AND COMMERCIALIZE OUR NEXT GENERATION OF VIBRANT SOUNDBRIDGE PRODUCTS, WE MAY NOT ACHIEVE PROFITABILITY.

Although we have offered the semi-implantable Vibrant Soundbridge for sale in Europe since 1998, we have not realized significant sales revenues to date. Our success depends on our ability to successfully commercialize an improved semi-implantable Soundbridge as well as a totally implantable Soundbridge. Our totally-implantable Soundbridge, currently under development, will require additional development, clinical trials and regulatory approval prior to commercialization. Successful completion of clinical trials for the totally-implantable Soundbridge products may never occur. Completion of clinical trials my be delayed by many factors, including research and development difficulties, slower than anticipated patient enrollment or adverse events occurring during clinical trials. Any delays in our clinical trials or any failure to obtain regulatory approval for these next generation Soundbridge products would impair our ability to achieve profitability.

### WE MAY NOT BE ABLE TO SECURE ADDITIONAL FUNDING TO SUPPORT OUR SUBSTANTIAL FUTURE CAPITAL REQUIREMENTS.

We will expend substantial funds in the future for research and development, preclinical and clinical testing, capital expenditures and the manufacturing, marketing and sale of our products. The timing and amount of spending of such capital resources cannot be accurately predicted and will depend upon several factors not within our control, including:

- market acceptance and demand for our products in the United States and internationally;
- the progress of our research and development efforts and preclinical and clinical activities;
- competing technological and market developments;
- the time and costs involved in obtaining regulatory approvals;
- the time and costs involved in filing, prosecuting and enforcing patent claims; and
- the progress and cost of commercialization of products currently under development.

We believe that our cash, cash equivalents and short-term investments at December 31, 2001 of approximately \$12.1 million will be sufficient to fund our operations and capital investments through 2002. However, we may require additional financing after that time. Such additional financing, if required, may not be available on a timely basis on terms acceptable to us, or at all. If adequate funds are not available, we could be required to delay development or commercialization of some of our products, to license to third parties the rights to commercialize some products or technologies that we would otherwise seek to commercialize for ourselves, or to reduce the marketing, customer support or other resources devoted to some of our products, any of which could have a material adverse effect on our business, financial condition and results of operations.

### IF WE DO NOT RECEIVE AND MAINTAIN REGULATORY APPROVALS FOR NEW PRODUCTS, WE WILL NOT BE ABLE TO MANUFACTURE OR MARKET NEW PRODUCTS.

Approval from the FDA is necessary to manufacture and market medical devices in the United States. Other countries have similar requirements. Since we have not realized significant revenues from sales of our current products, we must receive and maintain regulatory approval for new products or our business will fail.

The process that medical devices must undergo to receive necessary approval is extensive, time-consuming and costly, and there is no guarantee that regulatory authorities will approve any of our product candidates. FDA approval can be delayed, limited or not granted for many reasons, including:

• a product candidate may not be safe or effective;

- even if we believe data from preclinical testing and clinical trials should justify approval, FDA officials may disagree;
- the FDA might not approve our manufacturing processes or facilities or the processes or facilities of our contract manufacturers or raw material suppliers;
- the FDA may change its approval policies or adopt new regulations; and
- the FDA may approve a product candidate for indications that are narrow, which may limit our sales and marketing activities.

The process of obtaining approvals in foreign countries is subject to delay and failure for the same reasons.

WE FACE INTENSE COMPETITION IN OUR CURRENT AND POTENTIAL MARKETS AND IF WE CANNOT DEMONSTRATE THE SUPERIORITY OF OUR PRODUCTS, WE MAY FAIL TO ACHIEVE PROFITABILITY.

The medical device industry and the acoustic hearing aid market are subject to intense competition in the United States and abroad. We believe our products will compete primarily with hearing aids. Principal manufacturers of acoustic hearing aids include Siemens Hearing Instruments, Inc., Starkey Laboratories, Inc., GN ReSound, Inc., Oticon, Inc., Widex Hearing Aid Co., Inc., Sonic Innovations, Inc. and Phonak, Inc. Our products may not be as reliable or effective as established hearing aid products. If our products are not perceived as high quality, reliable and effective alternatives to conventional hearing aids, we may not successfully compete with established hearing aid products. Our competitors may also develop technologies and products in the future that are more reliable and effective and less expensive than those being developed by us or that do not require surgery.

Several companies have active research and development and marketing programs related to direct drive devices, which employ a middle ear implant designed to vibrate the small bones in the middle ear for sensorineural hearing loss. This type of hearing loss is the most common form of hearing loss that affects the majority of the 28 million people in the United States who suffers from hearing loss. Otologics, LLC, has developed a semi-implantable direct drive device for sensorineural hearing loss called the Middle Ear Transducer (MET). This device has begun the FDA regulatory process and initiated multicenter clinical trials. Otologics has recently obtained the CE Mark in Europe that allows the company to market and sell its product in Europe. Symphonix believes that St. Croix has begun clinical trials in Europe and has recently received an IDE approval to begin clinical studies on its fully implantable pizo electric device for sensorineural hearing loss. Soundtec, Inc., has completed clinical trials in the United States on a hybrid implantable/ear canal based hearing aid and has recently obtained FDA approval to market their product in the U.S. In addition, some large medical device companies, some of which are currently marketing implantable medical devices, may develop programs in hearing management. Many of these companies have substantially greater financial, technical, manufacturing, marketing and other resources than we have. If we fail to compete effectively with any or all of these companies and products, we will not achieve profitability.

OUR LACK OF SALES, MARKETING AND DISTRIBUTION EXPERIENCE COULD DELAY AND INCREASE THE COSTS OF INTRODUCING OUR SOUNDBRIDGE PRODUCTS INTO THOSE MARKETS WHERE WE HAVE RECEIVED REGULATORY APPROVALS.

In the United States, a direct sales force is concentrating our product marketing efforts on approximately 400 specialists in ear surgery and a targeted group of professional audiologists. In Europe, our sales and marketing effort is conducted through a distribution partnership with Siemens.

We may fail to build a direct sales force or marketing organization that is cost effective or successful in one or more countries. In addition, we have entered into distribution agreements with only a limited number of international distributors. There can be no assurance that we will be able to enter into similar agreements with

other qualified distributors on a timely basis on terms acceptable to us, or at all, or that such distributors will develop adequate resources to selling our products. If we fail to establish an adequate direct sales force domestically and in select international markets, and to enter into successful distribution relationships, we will have difficulty selling our products and our business may fail.

WE HAVE LIMITED MANUFACTURING EXPERIENCE, AND MAY BE UNABLE TO EXPAND OUR MANUFACTURING CAPABILITIES SUFFICIENTLY, WHICH COULD LIMIT OUR ABILITY TO DEVELOP AND DELIVER SUFFICIENT QUANTITIES OF PRODUCTS IN A TIMELY MANNER.

We currently manufacture our products in small quantities for commercial sales, laboratory testing and for clinical trials. The manufacture of our Soundbridge products is a complex operation involving a number of separate processes, components and assemblies. We have no experience manufacturing our products in the volumes or with the yields that will be necessary for us to achieve significant commercial sales, and there can be no assurance that we can establish high volume manufacturing capacity or, if established, that we will be able to manufacture our products in high volumes with commercially acceptable yields. We will need to expend significant capital resources and develop manufacturing expertise to establish commercial-scale manufacturing capabilities. Our inability to successfully manufacture or commercialize our Soundbridge products in a timely manner may harm our competitive position and market success.

### IF SIEMENS DOES NOT PERFORM ITS DUTIES UNDER OUR AGREEMENTS, OUR ABILITY TO COMMERCIALIZE OUR PRODUCTS MAY BE IMPAIRED.

We depend on Siemens Audiologische Technik GmbH to market and distribute our product in Europe. For the year ended December 31, 2001, the products sold under our marketing and distribution collaboration with Siemens in Europe accounted for approximately \$1.0 million or 48.3%, of our total product revenues over the same period. The marketing and distribution agreement which governs this arrangement remains effective until December 1, 2004, and is subject to automatic renewal for successive one-year periods thereafter unless terminated by either Symphonix or Siemens with at least 12 months' prior written notice. The marketing and distribution agreement may be terminated sooner if Symphonix or Siemens fails to cure a material breach within 30 days' of notice of the breach, upon insolvency or bankruptcy of Symphonix or Siemens, or if Symphonix is acquired.

We also depend on Siemens to provide integrated circuits and software for use in our Soundbridge products. The supply agreement which governs this arrangement remains effective until September 30, 2004, and is subject to automatic renewal for successive one-year periods thereafter unless terminated by either Symphonix or Siemens with at least three months' prior written notice. The supply agreement may also be terminated sooner if Symphonix or Siemens fails to cure a material breach within 30 days' of notice of the breach. In addition to marketing and distributing our products in Europe, Siemens also manufactures and distributes its own acoustic hearing aids. Since the hearing aids manufactured and distributed by Siemens are competitive products to our Soundbridge products, Siemens could have an incentive to breach or terminate our agreements. Termination or breach by Siemens of either its marketing and distribution agreement or supply agreement with us could delay or stop the commercialization of our products.

WE RELY ON SEVERAL SOLE SOURCE OR LIMITED SOURCE SUPPLIERS, AND OUR PRODUCTION WILL BE SERIOUSLY HARMED IF THESE SUPPLIERS ARE NOT ABLE TO MEET OUR DEMAND AND ALTERNATIVE SOURCES ARE NOT AVAILABLE.

A number of components and sub-assemblies, such as silicone, signal processing electronics implant packaging, as well as sterilization services are provided by single source suppliers. Furthermore, the key analog and digital signal processing microcircuits of the Vibrant P, Model 302, Vibrant D, Model 304 and Vibrant D, Model 404 Soundbridges are provided by sole source suppliers. None of our suppliers is contractually obligated to continue to supply us nor are we contractually obligated to buy from a particular supplier. For some of these

components and sub-assemblies, there are relatively few alternative sources of supply, and we cannot quickly establish additional or replacement suppliers for such components and sub-assemblies. In addition, additional approvals will be required form the FDA before we can significantly modify our manufacturing processes or change the supplier of a critical component. Because of the long lead time for some components and subassemblies that are currently available from a single source, a supplier's inability or failure to supply such components or subassemblies in a timely manner or our decision to change suppliers could have a material adverse effect on our business, financial condition and results of operation.

IF WE ARE UNABLE TO PROTECT OUR INTELLECTUAL PROPERTY, OUR COMPETITORS COULD DEVELOP AND MARKET PRODUCTS WITH SIMILAR FEATURES THAT MAY REDUCE DEMAND FOR OUR PRODUCTS.

Our success depends in part on our ability to protect our issued and pending patents, trade secrets and other intellectual property. The strength of this protection is uncertain. Our competitors could challenge, invalidate or circumvent our issued patents as well as any future patents. Even if upheld, our issued patents may not exclude competitors or otherwise provide competitive advantages to us.

In addition, a competitor may obtain patents that will interfere with our ability to make, use or sell our products either in the United States or in international markets. There may be pending applications, which if issued, might provide proprietary rights to third parties relating to products or processes used or proposed to be used by us. We may be required to obtain licenses to patents or proprietary rights of others. Further, the laws of some foreign countries do not protect our intellectual property rights to the same extent as do the laws of the United States. Litigation or regulatory proceedings, which could result in substantial cost and uncertainty to us, may also be necessary to enforce our patent or other intellectual property rights or to determine the scope and validity of other parties' proprietary rights. We may not have the financial resources to defend our patents from infringement or claims of invalidity.

We also rely upon trade secrets and other unpatented proprietary technology. Our competitors may independently develop substantially equivalent proprietary information and techniques or otherwise gain access to or disclose our proprietary technology. Our policy is to require each of our employees, consultants, investigators and advisors to execute a confidentiality agreement upon commencement of an employment or consulting relationship with us. However, these agreements may not provide meaningful protection for our proprietary information in the event of unauthorized use or disclosure of such information.

Title 35, Section 287 of the United States Code limits the enforcement of patents relating to the performance of surgical or medical procedures on a body. This law precludes medical practitioners and health care entities, which practice these procedures, from being sued for patent infringement. Therefore, depending upon how these limitations are interpreted by the courts, they could have a material adverse effect on our ability to enforce any of our proprietary methods or procedures deemed to be surgical or medical procedures on a body. In some countries other than the United States, patent coverage relating to the performance of surgical or medical procedures is not available. Therefore, patent coverage in such countries will be limited to the Floating Mass Transducer, the patented core direct drive technology upon which all of our Soundbridge products are based, or to narrower aspects of the Floating Mass Transducer.

The medical device industry in general has been characterized by substantial litigation. Litigation regarding patent and other intellectual property rights, whether with our without merit, could be time-consuming and expensive to respond to and could distract our technical and management personnel. Symphonix has filed a complaint against Soundtec, Inc., the Central Ear Research Institute (CERI) and three senior Soundtec executives alleging actions that include misappropriation of trade secrets, breach of contract and inducing breach of contract. Central to the complaint is Symphonix's contention that Soundtec and its three executives utilized Symphonix's confidential, proprietary and trade secret information to develop and market the Direct System<sup>TM</sup>, Soundtec's implantable middle ear hearing device. Prior to their tenure at Soundtec, the three executives named

in the complaint were employed by CERI, which, in December 1994, entered into an agreement to undertake a research and development project with Symphonix on the development of an implantable hearing device. The agreement permanently transferred exclusive rights to Symphonix for all technology developed during the research period. It further required that CERI disclose and permanently transfer rights to Symphonix for all improvements invented, development or otherwise acquired by CERI for five years after termination of the agreement. Two of the named executives in the complaint executed this agreement on CERI's behalf. Soundtec was founded in March 1997, five months after CERI terminated its agreement with Symphonix. Among other requests, Symphonix is seeking to restrain Soundtec from selling its Direct System device for a period of two years and to collect related damages.

We may also become involved in litigation to enforce our patents or to defend against claims of infringement. If any relevant claims of third-party patents are held as infringed and not invalid in any litigation or administrative proceeding, we could be prevented from practicing the subject matter claimed in such patents, or would be required to obtain licenses from the patent owners of each such patent, or to redesign our products or processes to avoid infringement. In addition, in the event of any possible infringement, there can be no assurance that we would be successful in any attempt to redesign our products or processes to avoid such infringement or in obtaining licenses on terms acceptable to us, if at all. Accordingly, an adverse determination in a judicial or administrative proceeding or failure by us to redesign our products or processes or to obtain necessary licenses could prevent us from manufacturing and selling our products, which would have a material adverse effect on our business, financial condition and results of operations. Although we have not been involved in any litigation to date, in the future, costly and time-consuming litigation brought by us may be necessary to enforce patents issued to us, to protect our trade secrets or know-how, or to determine the enforceability, scope and validity of the proprietary rights of others.

### IF WE CANNOT RETAIN OR HIRE KEY PERSONNEL, OUR BUSINESS WILL SUFFER.

Our future success depends in significant part upon the continued service of key scientific, technical, sales and marketing, and management personnel. Competition for such personnel is intense. There can be no assurance that we can retain our key scientific, technical, sales and marketing and managerial personnel or that we can attract, assimilate or retain other highly qualified scientific, technical, sales and marketing, and managerial personnel in the future. The loss of key personnel, especially if without advance notice, or the inability to hire or retain qualified personnel could impair our ability to commercialize our Vibrant Soundbridge products and develop future products.

### COMPLICATIONS MAY RESULT FROM THE USE OF OUR SOUNDBRIDGE PRODUCTS, AND INSURANCE MAY BE INSUFFICIENT OR UNAVAILABLE TO COVER POTENTIALLY SIGNIFICANT PRODUCT LIABILITY EXPENSES IF WE ARE SUED.

Our business involves the inherent risk of product liability claims. We maintain limited product liability insurance at coverage levels which we believe to be commercially reasonable and adequate given our current operations. However, this insurance may not be available in the future on commercially reasonable terms, or at all. Even if it is available, it may not be adequate to cover liabilities that may arise. If we are sued for an injury caused by our products, the resulting liability could result in significant expense, which could harm our business and financial condition.

### OUR INTERNATIONAL SALES AND OPERATION EXPOSE US TO FOREIGN CURRENCY AND POLITICAL RISKS.

We may continue to expand our operations outside of the United States and may enter additional international markets, which would require significant management attention and financial resources and subject us further to the risks of operating internationally. These risks include:

· unexpected changes in regulatory requirements;

- delays resulting from difficulty in obtaining export licenses for certain technology;
- tariffs and other barriers and restrictions:
- the burdens of complying with a variety of foreign laws and regulations; and
- · difficulty in staffing and managing international operations.

We would also be subject to general political and economic risks if we expand our international operations, such as political instability, changes in diplomatic and trade relationships and general economic fluctuations in specific countries or markets.

We cannot predict whether quotas, duties, taxes, or other charges or restrictions will be imposed by the United States, the European Union, Japan, or other countries upon the import or export of our products in the future, or what effect any such actions would have on our business, financial condition or results of operations. There can be no assurance that regulatory, geopolitical and other factors will not adversely affect our business in the future or require us to modify our current business practices.

In addition, because most of our international sales, and a large portion of the associated expenses, are denominated in foreign currencies, gains and losses on the conversion to U.S. dollars of accounts receivable and accounts payable arising from international operations may contribute to fluctuations in our operating results. Further, fluctuations in currency exchange rates may negatively impact our ability to compete in terms of price against products denominated in local currencies. To date, we have not found it appropriate to hedge the risks associated with fluctuations in exchange rates. However, even if we undertake such transactions in the future, they may fail.

### ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Symphonix considered the provisions of Financial Reporting Release No. 48 "Disclosure of Accounting Policies for Derivative Financial Instruments and Derivative Commodity Instruments, and Disclosure of Quantitative and Qualitative Information about Market Risk Inherent in Derivative Financial Instruments, Other Financial Instruments and Derivative Commodity Instruments". Symphonix had no holdings of derivative financial or commodity instruments at December 31, 2001. Symphonix is exposed to financial market risks, including changes in interest rates and foreign currency exchange rates. The fair value of Symphonix's investment portfolio or related income would not be significantly impacted by either a 100 basis point increase or decrease in interest rates due mainly to the short-term nature of Symphonix's investment portfolio. Symphonix's debt obligations are subject to interest rate risk but due to the minimal amount of debt, this risk is insignificant. An increase in interest rates would not significantly affect the Company's net loss. Much of the Company's revenue and all of its capital spending is transacted in U.S. dollars. However, the Company does enter into transactions in other currencies, primarily the Euro. Gains and losses on the conversion to U.S. dollars of accounts receivable and accounts payable resulting from these transactions may contribute to fluctuations in our operating results. However, these transactions in other currencies were not material relative to transactions in U.S. dollars. At December 31, 2001, the Company performed sensitivity analyses to assess the potential effect of this risk and concluded that near-term changes in interest rates and foreign currency exchange rates should not materially adversely affect the Company's financial position, results of operations or cash flows.

### ITEM 8. CONSOLIDATED FINANCIAL STATEMENTS

The consolidated financial statements as of December 31, 2001 and for the years ended December 31, 2001 and 1999 and the related report of PricewaterhouseCoopers LLP, independent accountants and the consolidated financial statements as of and for the year ended December 31, 2000 and the related report of KPMG LLP, independent auditors are included on the following pages.

### REPORT OF INDEPENDENT ACCOUNTANTS

To the Board of Directors and Stockholders of Symphonix Devices, Inc.:

In our opinion, the consolidated financial statements listed in the index appearing under Item 14(a)(1) on page 59, present fairly, in all material respects, the financial position of Symphonix Devices, Inc. and its subsidiaries at December 31, 2001, and the results of their operations and their cash flows for each of the years ended December 31, 2001 and 1999 in conformity with accounting principles generally accepted in the United States of America. In addition, in our opinion, the financial statement schedule listed in the index appearing under Item 14(a)(2) on page 59, presents fairly, in all material respects, the information set forth therein for each of the years ended December 31, 2001 and 1999 when read in conjunction with the related consolidated financial statements. These financial statements and financial statement schedule are the responsibility of the Company's management; our responsibility is to express an opinion on these financial statements based on our audits. We conducted our audits of these statements in accordance with auditing standards generally accepted in the United States of America, which require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, and evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

/s/ PRICEWATERHOUSECOOPERS LLP

San Jose, California January 25, 2002

### REPORT OF INDEPENDENT AUDITORS

To the Board of Directors and Stockholders of Symphonix Devices, Inc.

We have audited the accompanying consolidated balance sheet of Symphonix Devices, Inc. and subsidiaries as of December 31, 2000 and the related consolidated statements of operations, stockholders' equity, comprehensive loss, and cash flows for the year then ended. In connection with our audit of the consolidated financial statements, we have also audited the related consolidated financial statement schedule as it relates to the year ended December 31, 2000 listed in the index appearing under Item 14(a)(2) on page 59 of the accompanying Form 10-K. These consolidated financial statements and the related financial statement schedule are the responsibility of Symphonix's management. Our responsibility is to express an opinion on the consolidated financial statements and the related financial statements chedule based on our audit.

We conducted our audit in accordance with auditing standards generally accepted in the United States of America. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audit provides a reasonable basis for our opinion.

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the financial position of Symphonix Devices, Inc. and subsidiaries at December 31, 2000 and the results of their operations and their cash flows for the year then ended, in conformity with accounting principles generally accepted in the United States of America. Also, in our opinion, the related consolidated financial statement schedule, when considered in relation to the basic consolidated financial statements taken as a whole, present fairly, in all material respects, the information set forth therein.

/s/ KPMG LLP

San Francisco, California February 14, 2001

### CONSOLIDATED BALANCE SHEETS (in thousands, except share and per share data)

	Decem	ber 31,
	2001	2000
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 1,343	\$ 29,264
Short-term investments	10,774	
Accounts receivable, net of allowance for doubtful accounts		
of \$27 in 2001 and \$7 in 2000	329	356
Inventories	656	2,034
Prepaid expenses and other current assets	566	634
Total current assets	13,668	32,288
Property and equipment, net	1,313	1,396
Restricted cash	174	271
Other assets		75
Total assets	\$ 15,155	\$ 34,030
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	\$ 451	\$ 834
Accrued compensation	976	1,304
Other accrued liabilities	2,708	3,772
Current portion of bank borrowing	500	500
Total current liabilities	4,635	6,410
Deferred revenue	732	1,101
Bank borrowings, less current portion	500	1,000
Total liabilities	5,867	8,511
Commitments (Note 5)		
Stockholders' equity:		
Convertible preferred stock, \$.001 par value:		
Authorized: 5,000,000 shares		
Issued and outstanding: no shares in 2001 and 2000	_	_
Common stock, \$.001 par value:		
Authorized: 50,000,000 shares		
Issued and outstanding: 35,635,000 shares in 2001 and		
20,912,000 shares in 2000	36	21
Notes receivable from stockholders	(400)	(421)
Deferred compensation	02 107	(34)
Additional paid-in capital	92,107 260	91,885 54
Accumulated deficit	(82,715)	(65,986)
Total stockholders' equity	9,288	25,519
Total liabilities and stockholders' equity	\$ 15,155	\$ 34,030

The accompanying notes are an integral part of these consolidated financial statements.

### CONSOLIDATED STATEMENTS OF OPERATIONS

(in thousands, except per share data)

	Year Ended December 31,		
	2001	2000	1999
Revenues	\$ 2,020	\$ 1,247	\$ 331
Costs and expenses:			
Costs of goods sold	4,280	3,094	4,078
Research and development	6,104	7,119	7,848
Selling, general and administrative	9,158	8,654	5,847
Total costs and expenses	19,542	18,867	17,773
Operating loss	(17,522)	(17,620)	(17,442)
Interest income	894	652	821
Interest expense	(101)	(189)	(58)
Net loss	<u>\$(16,729)</u>	<u>\$(17,157)</u>	<u>\$(16,679)</u>
Basic and diluted net loss per common share	\$ (0.60)	\$ (1.18)	\$ (1.35)
share	27,798	14,594	12,393

The accompanying notes are an integral part of these consolidated financial statements.

### CONSOLIDATED STATEMENTS OF CASH FLOWS (in thousands)

	Year E	Inded Decemi	per 31,
	2001	2000	1999
Cash flows from operating activities:			
Net loss	\$(16,729)	\$(17,157)	\$(16,679)
Amortization of deferred compensation	34	295	517
Amortization of premium on investments	155	_	
Stock based compensation	_	40	
Allowance for doubtful accounts	20	_	52
Depreciation and amortization	751	766	766
Loss on disposal of fixed assets	11	_	
Accounts receivable	7	(239)	59
Inventories	1,378	(1,372)	99
Prepaid expenses and other current assets	124	` 46	13
Accounts payable	(383)	260	(110)
Accrued compensation	(328)	143	101
Deferred revenue	(369)	(319)	1,420
Other accrued liabilities	(994)	1,746	1,275
Net cash used in operating activities	(16,323)	(15,791)	(12,487)
Cash flows from investing activities:		<del></del>	
Purchases of short-term investments	(27,380)	(3,656)	(4,650)
Maturities of short-term and long-term investments	16,631	10,550	19,248
Purchases of property and equipment	(749)	(608)	(220)
Change in restricted cash	97	(271)	(220)
Change in other assets	19	3	_
Net cash provided by (used in) investing activities	(11,382)	6,018	14,378
Cash flows from financing activities:			
Payments on capital lease obligations	_	(98)	(227)
Payments on bank borrowings	(500)	(500)	` <b>_</b> ′
Proceeds from issuance of common stock, net of issuance costs	237	31,025	3,342
Issuance of notes receivable from stockholders	_	(160)	(370)
Payments received on notes receivable from stockholders	21		
Net cash provided by (used in) financing activities	(242)	30,978	2,745
Net increase (decrease) in cash and cash equivalents	(27,947)	21,205	4,636
Effect of exchange rates on cash and cash equivalents	26	61	(39)
Cash and cash equivalents, beginning of year	29,264	7,998	3,401
Cash and cash equivalents, end of year	\$ 1,343	\$ 29,264	\$ 7,998
Supplemental disclosure of cash flow information and non-cash activities			
Cash paid for interest	\$ 101	\$ 189	\$ 58
Common stock issued in exchange for promissory note	<u> </u>	<u>\$</u>	\$ 225
Reversal of unrealized deferred compensation	<u> </u>	\$ 411	\$ 260
Cancellation of notes receivable to stockholders for unvested restricted			
stock	<u>\$</u>	\$ 107	<u>\$ —</u>

The accompanying notes are an integral part of these consolidated financial statements

# CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY For the three years ended December 31, 2001 (in thousands, except per share data)

	Common Stock	Stock	Receivable From	Deferred	Paid-In	Comprehensive	Accumulated	Total Stockholders'
•	Shares	Amount	Stockholders	Compensation	Capital	Income (Loss)	Deficit	Equity
Balances, December 31, 1998  Private placement, net of issuance costs  Note receivable issued to stockholder	12,201	\$12 1	\$ (484)	\$(1,517)	\$58,040 3,159	\$ (26)	\$(32,150)	\$23,875 3,160
Common stock issued in connection with stock option exercises  Common stock issued pursuant to Company's stock purchase plan.  Common stock issued in connection with stock option exercises for	62 80				52 130			525 130
notes receivable. Cancellations of stock options	100		(225)	260	225 (260)			;
Amortization of deterred compensation  Change in unrealized losses on investments  Translation adjustments  Nat loss				21.7		9 (39)	(019 91)	517 $9$ $(39)$
Balances, December 31, 1999	13,443	13	(1,079)	(740)	61,346	(56)	(48,829)	10,655
Note receivable issued to stockholder	(134)		(160)	-	(107)			(160)
Amortization of deferred compensation Stock based compensation	•			295	(411)			295 40
Common stock issued in connection with warrant exercises	<u> </u>				145			145
Private placement, not of issuance costs.  Change in unrealitized losses on investments.	7,424	∞			30,714	49		30,722 49
Translation adjustments Net loss						19	(17,157)	61 (17,157)
Balances, December 31, 2000	20,912	21	(421)	(34)	91,885	54	(65,986)	25,519
Repurchase of common stock	(3)		21		(2)			(2)
Amortization of deferred compensation	172			34	221			34 221
Common stock issued pursuant to purchase price adjustment, net of issuance costs	14,336	15			(129)			(114)
Common stock issued pursuant to the Company's stock purchase plan Change in unrealized gains on investments	218				132	180		132 180
Net loss						97	(16,729)	26 (16,729)
Balances, December 31, 2001	35,635	\$36	\$ (400)	   <del>\$</del>	\$92,107	\$260	\$(82,715)	\$ 9,288

The accompanying notes are an integral part of these consolidated financial statements

### CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS (in thousands)

	Year Ended December 31,			
	2001	2000	1999	
Net loss	\$(16,729)	\$(17,157)	\$(16,679)	
Change in unrealized gains (losses) on short-term investments	180	49	9	
Translation adjustments	26	61	(39)	
Comprehensive loss	\$(16,523)	<u>\$(17,047)</u>	<u>\$(16,709)</u>	

### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

### 1. Formation and Business of Symphonix:

Symphonix Devices, Inc. (the "Company" or "Symphonix") was incorporated on May 17, 1994 to develop and manufacture implantable and semi-implantable hearing devices. Symphonix sells products in North America and Europe through its direct sales force and distributors.

### Liquidity

These consolidated financial statements contemplate the realization of assets and the satisfaction of liabilities in the normal course of business. Symphonix's commercial operations commenced during 1998. Symphonix has sustained significant losses for the last several years and there can be no assurance that Symphonix will attain profitability.

At December 31, 2001, Symphonix had aggregate consolidated net losses of approximately \$82.7 million. Symphonix expects negative cash flow from operations to continue through 2002, with the need for funding additional development of the Vibrant Soundbridge system, conducting clinical trials required for FDA clearance of new products, continued marketing and sales capabilities and administrative infrastructure. Beginning in late 2001 and continuing into 2002, Symphonix has instituted a series of actions to rationalize its operations to provide lower operating costs while increasing efficiencies. If revenue growth does not match projections, Symphonix will take actions necessary to reduce fixed costs commensurate with the level of revenue achieved. As a result of these actions, management believes that its existing cash balances and other potential financing alternatives will be sufficient to meet its capital and operating requirements through at least 2002.

Symphonix's commercial operations commenced during 1998. Symphonix has sustained significant losses for the last several years. Symphonix will require additional funding and may sell additional shares of its common stock or preferred stock through private placement or further public offerings. There can be no assurance that Symphonix will be able to obtain additional debt or equity financing, if and when needed, on terms acceptable to Symphonix. Any additional equity or debt financing may involve substantial dilution to Symphonix's stockholders, restrictive covenants or high interest costs. The failure to raise needed funds on sufficiently favorable terms could have a material adverse effect on Symphonix's business, operating results and financial condition. Symphonix's long-term liquidity also depends upon its ability to increase revenues from the sale of its products and achieve profitability. The failure to achieve these goals could have a material adverse effect on the operating results and financial condition of Symphonix.

### 2. Summary of Significant Accounting Policies:

### Basis of Consolidation:

The consolidated financial statements include the accounts of Symphonix and its wholly-owned subsidiaries. All significant intercompany accounts and transactions have been eliminated.

### Use of Estimates:

The preparation of financial statements in conformity with accounting principles generally accepted in the United States of America requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting periods. Actual results could differ from those estimates.

### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)

### Concentration of Credit Risk and Other Risks and Uncertainties:

Symphonix's cash and cash equivalents are primarily maintained at two financial institutions in the United States. Deposits held with banks may exceed the amount of insurance provided on such deposits. Generally these deposits may be redeemed upon demand and therefore, bear minimal risk.

Symphonix performs ongoing credit evaluations of its customers and maintains an allowance for doubtful accounts. Historically Symphonix has not experienced significant losses related to individual customers. At December 31, 2001 and 2000 one customer accounted for approximately 60.0% and 71.9%, respectively, of accounts receivable.

Symphonix's products require approvals from the FDA and international regulatory agencies prior to commercial sales. During 2000, Symphonix received approvals to market its Vibrant Soundbridge in the United States. There can be no assurance that Symphonix's future products will receive additional required approvals. If Symphonix is denied such approvals or if such approvals are delayed, it would have a materially adverse impact on Symphonix.

Symphonix relies on several sole source or limited source suppliers and its production could be seriously harmed if these suppliers are not able to meet its demand and alternative sources are not available.

### Fair value of Financial Instruments:

Carrying amounts of certain of Symphonix's financial instruments including cash and cash equivalents, short-term investments, accounts receivable and accounts payable approximate fair values due to their short maturities. Based on the borrowing rates currently available to Symphonix for loans with similar terms, the carrying value of the bank loan approximates fair value. Estimated fair values for short-term investments, which are separately disclosed elsewhere, are based on quoted market prices for the same or similar instruments.

### Cash and Cash Equivalents and Restricted Cash:

Symphonix considers all highly liquid investments purchased with original maturities of three months or less to be cash equivalents. Restricted cash consists of certificates of deposit held with a financial institution as a security deposit for a building lease and in connection with a loan agreement.

### Investments:

All investments are classified as available-for-sale and therefore are carried at fair market value. Unrealized gains and losses on such securities are reported as a separate component of other comprehensive income (loss). Interest income is recorded using an effective interest rate, with associated premium or discount amortized to interest income. Realized gains and losses on sales of all such securities are reported in earnings and computed using the specific identification cost method. All investments with maturity dates greater than one year are classified as long term.

### Inventories:

Inventories are stated at the lower of cost or market. Cost is determined on a standard cost basis that approximates the first-in, first-out (FIFO) method. Appropriate consideration is given to obsolescence, excessive levels, deterioration and other factors in evaluating lower of cost or market.

### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)

### Property and Equipment:

Property and equipment are stated at cost less accumulated depreciation and amortization. Depreciation is provided on a straight-line basis over the estimated useful lives of the assets, which is generally three to five years. Amortization of leasehold improvements and property and equipment under capital lease obligations is computed using the straight-line method over the shorter of the remaining lease term or the estimated useful life of the related assets, typically five years. Upon retirement or disposal of the asset, the cost and related accumulated depreciation are removed from the balance sheet and any related gain or loss is reflected in operations. Maintenance and repairs are charged to operations as incurred.

### Long-Lived Assets:

Symphonix periodically reviews the value of long-lived assets for impairment whenever events or changes in business circumstances indicate that the carrying amount of the assets may not be fully recoverable or that the useful lives of these assets are no longer appropriate. Each impairment test is based on a comparison of the future undiscounted cash flows arising from the assets with the carrying value of the asset. If an impairment is indicated, the asset is written down to its estimated fair value on a discounted cash flow basis. Since inception through December 31, 2001, no impairment losses have been identified.

### Income Taxes:

Symphonix accounts for income taxes under the asset and liability method, whereby deferred tax assets and liabilities are determined based on the difference between the financial statement and tax bases of assets and liabilities using enacted tax rates in effect for the year in which the differences are expected to affect taxable income. Valuation allowances are established when necessary to reduce deferred tax assets to the amounts expected to be realized.

### Foreign Currency Translation:

Symphonix's international subsidiaries use their local currency as their functional currency. Assets and liabilities are translated at exchange rates in effect at the balance sheet date and income and expense accounts at average exchange rates during the year. Resulting translation adjustments are recorded directly to a separate component of other comprehensive income (loss). Foreign currency transaction gains and losses are included in results of operations and have been immaterial for all periods presented.

### Revenue Recognition:

Symphonix recognizes revenue in accordance with Staff Accounting Bulletin No. 101, "Revenue Recognition in Financial Statements." Revenue from product sales is recognized upon shipment of product against a valid purchase order provided no significant obligations remain and collection of the receivables are deemed probable. Upon shipment, Symphonix provides for estimated product returns and estimated costs that may be incurred for product warranties. Amounts received prior to completion of the earnings process are recorded as deferred revenue and recognized on a straight line basis over the life of the agreement. Included in revenues are \$0.4 million, \$0.4 million and zero for the years ended December 31, 2001, 2000 and 1999, respectively, which represents the amortization of the premium of \$1,885,000 on the common stock purchased by Siemens in accordance with the Marketing and Distribution Agreement (Note 6).

### Research and Development:

Research and development costs are charged to operations as incurred. Legal expenses relating to patent costs are expensed as incurred.

### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)

### Accounting for Stock-Based Compensation:

The Company accounts for stock-based employee compensation arrangements in accordance with provisions of Accounting Principles Board Opinion No. 25 ("APB 25"), "Accounting for Stock Issued to Employees" and related interpretations and complies with the disclosure provisions of Statement of Financial Accounting Standards No. 123 ("SFAS 123"), "Accounting for Stock—Based Compensation."

Under APB 25, compensation expense is based on the difference, if any, on the date of the grant, between the fair value of the Company's stock and the exercise price. SFAS 123 defines a "fair value" based method of accounting for an employee stock option or similar equity investment.

The Company accounts for equity instruments issued to non-employees in accordance with the provisions of SFAS 123 and Emerging Issues Task Force Issue No. 96-18 ("EITF 96-18"), "Accounting for Equity Instruments That Are Issued to Other Than Employees for Acquiring, or in Conjunction with Selling, Goods or Services" and Financial Accounting Standards Board Interpretation No. 28 ("FIN 28"), "Accounting for Stock Appreciation Rights and Other Variable Stock Option or Award Plans."

### Computation of Earnings per Share:

Basic earnings per share ("EPS") is computed by dividing net loss by the weighted average number of common shares outstanding for the period. Diluted EPS reflects the potential dilution that could occur from common shares issuable through stock options, warrants and other convertible securities, if dilutive. The following table is a reconciliation of the numerator (net loss) and the denominator (number of shares) used in the basic and diluted EPS calculations and sets forth potential shares of common stock that are not included in the diluted net loss per share calculation as their effect is antidilutive (in thousands, except for per share data):

	Year E	Year Ended December 31,		
	2001	2000	1999	
Numerator—Basic and Diluted net loss	\$(16,729)	\$(17,157)	\$(16,679)	
Denominator—Basic and Diluted  Weighted average common shares outstanding  Weighted average unvested common shares subject to repurchase  Total	27,853 (55) 27,798	14,674 (80) 14,594	12,492 (99) 12,393	
Net loss per common share	\$ (0.60)	\$ (1.18)	\$ (1.35)	
Antidilutive securities: Options to purchase common stock Common stock subject to repurchase Warrants	3,426 42 7 3,475	2,915 67 7 2,989	1,704 92 34 1,830	

### Reclassification:

Certain prior year financial statement items have been reclassified to conform to the current year's presentation.

### Recent Accounting Pronouncements:

In July 2001, the Financial Accounting and Standards Board ("FASB") issued Statements of Financial Accounting Standards No. 141 ("SFAS 141"), "Business Combinations," and No. 142 ("SFAS 142"), "Goodwill

### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)

and Other Intangible Assets." SFAS 141 requires that all business combinations initiated after June 30, 2001 be accounted for under a single method—the purchase method. Use of the pooling-of-interests method is no longer permitted. SFAS 142 requires that goodwill no longer be amortized to earnings, but instead be reviewed for impairment upon initial adoption of the Statement and on an annual basis going forward. The amortization of goodwill will cease upon adoption of SFAS 142. The provisions of SFAS 142 will be effective for fiscal years beginning after December 15, 2001. Management believes that SFAS 142 will not have a material effect on the financial position or results of operations of the Company.

In October 2001, the FASB issued Statement of Financial Accounting Standards No. 144 ("SFAS 144"), "Accounting for the Impairment or Disposal of Long-Lived Assets," which is effective for fiscal years beginning after December 15, 2001 and interim periods within those fiscal periods. SFAS 144 supersedes FASB Statement No. 121 and APB Opinion No. 30, however, it retains the requirement of Opinion No. 30 to report discontinued operations separately from continuing operations and extends that reporting to a component of an entity that either has been disposed of (by sale, by abandonment, or in a distribution to owners) or is classified as held for sale. SFAS 144 addresses financial accounting and reporting for the impairment of certain long-lived assets and for long-lived assets to be disposed of. Management believes that SFAS 144 will not have a material impact on the financial position or results of operations of the Company.

### 3. Balance Sheet Detail:

### Investments:

As of December 31, 2001, short-term investments consisted of the following (in thousands):

	De	cember 31, 20	01	
	Amortized Cost	Unrealized Gains	Estimated Fair Value	Maturity Dates
Commercial paper	\$10,594	\$180	\$10,774	05/2002-08/2002

Realized gains on sales of short-term investments in 2001 were \$46,000. There were no realized gains or losses recognized on the sale of short-term investments in 2000 and 1999.

As of December 31, 2000, there were no short-term investments.

### Inventories:

Inventories are comprised of the following (in thousands):

	Decer	nber 31,
	2001	2000
Raw Materials	\$227	\$ 253
Work-in-Process	340	1,097
Finished Goods	89	684
	\$656	\$2,034

### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)

### Property and Equipment:

Property and equipment consist of the following (in thousands):

	December 31,	
	2001	2000
Furniture and fixtures	\$ 412	\$ 452
Machinery and equipment	2,737	2,735
Leasehold improvements	1,140	1,140
Software	340	214
	4,629	4,541
Less accumulated depreciation and amortization	(3,316)	(3,145)
	\$ 1,313	\$ 1,396

### Other accrued Liabilities:

Other accrued liabilities comprise (in thousands):

		Decem	ber 31,
		2001	2000
Professional fees	\$	499	\$ 679
Clinical trials		550	588
Deferred revenue		377	377
Warranty		840	1,119
Restructuring (Note 9)		_	509
Other		442	500
	\$2	2,708	\$3,772

### 4. Bank Borrowings:

Symphonix has a Loan Agreement with a bank providing for borrowings of up to \$2,000,000 and the issuance of letters of credit up to \$250,000. The principal amount is being repaid over four years. Borrowings under the agreement bear interest at the bank's prime rate plus 0.75% and are collateralized by substantially all of Symphonix's assets. Symphonix is required to maintain certain levels of cash and stockholders' equity and to comply with certain other financial covenants.

At December 31, 2001, Symphonix had borrowings outstanding of \$1,000,000, outstanding letters of credit in the amount of \$174,000 and no amounts available for future borrowings under the Loan Agreement.

Future payments of principal under the Loan Agreement are as follows (in thousands):

2002	\$	500
2003		500
	\$1	,000

### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)

### 5. Commitments:

Symphonix rents its primary facilities under an operating lease that expires in December 2002. Under the terms of the lease, Symphonix is responsible for certain taxes, insurance and maintenance expenses.

Future minimum rental payments under all operating leases as of December 31, 2001 are as follows (in thousands):

Rent expense for the years ended December 31, 2001, 2000 and 1999 was \$635,000, \$674,000, and \$654,000, respectively.

### 6. Stockholders' Equity:

Private Placement:

In November 1999, Symphonix consummated a \$5,000,000 private placement of 1,000,000 shares of Symphonix's common stock to Siemens at a purchase price of \$5.00 per share in connection with a Marketing and Distribution Agreement. In September 2000 in accordance with the Marketing and Distribution Agreement, Siemens purchased an additional 1,026,062 shares of Symphonix's common stock at a purchase price of \$4.87 per share resulting in gross proceeds of \$5,000,000. The number of shares and purchase price were determined by dividing \$5,000,000 by the average of the closing sales prices of Symphonix's common stock as reported by the NASDAQ National Market for the forty (40) trading days immediately preceding the public announcement of the FDA grant of premarket approval of Symphonix's Vibrant P, Model 302 and Vibrant D, Model 304 Soundbridges. In conjunction with this agreement and in the event of a change in control, Symphonix has the right to terminate the agreement by paying a) \$1.0 million or 2 times Siemen's prior 12 months revenue of Symphonix's products if terminated during the first or second year of the contract, b) \$1.0 million or 1.5 times Siemen's revenue of Symphonix's products if terminated during the third year of the contract, or c) \$2.0 million or 1 times Siemen's revenue of Symphonix's products if terminated during the fourth or fifth year of the contract. The purchase price for the private placement exceeded the fair market value of Symphonix's common stock as reported on the NASDAQ National Market on the date of issuance. The difference between the purchase price and the fair market value of Symphonix's common stock has been recorded as deferred revenue and is being amortized to revenue on a straight-line basis over the term of the agreement.

In November 2000, Symphonix consummated a \$26,000,000 private placement through a transaction led by APAX Partners ("APAX") and J.P. Morgan Capital, LP ("J.P. Morgan"). The shares of common stock issued in the financing were priced at \$4.064 per share, which was determined as 80% of the average of the closing price of Symphonix's common stock for the thirty-three (33) day period ending on September 18, 2000. Accordingly, a total of 6,397,632 shares of common stock was issued to the investors at the closing of the financing.

The terms of the private placement detailed in the Common Stock Purchase Agreement provided for a purchase price adjustment that allowed the investors to calculate, one time prior to November 10, 2002, an adjusted per share purchase price equal to the average closing market price of Symphonix common stock as reported on the NASDAQ National Market for the thirty-three (33) consecutive trading days immediately preceding the date of adjustment. Those investors participating in the adjustment would receive additional shares of common stock, for no additional consideration, equal to the difference between the number of shares which each investor could have purchased based on the adjusted per share purchase price at the investor's original investment amount and the number of shares originally purchased.

### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)

On June 25, 2001, certain investors notified Symphonix that they were exercising their purchase price adjustment pursuant to the Common Stock Purchase Agreement. All investors agreed to participate in the adjustment, and on July 12, 2001, Symphonix subsequently issued, for no additional consideration, an additional 14,336,020 shares to the investors based on an adjusted per share purchase price of approximately \$1.254.

Issuance costs for the 2000 equity placements were approximately \$270,000.

So long as J.P. Morgan and APAX each hold at least 1,203,315 shares of common stock, Symphonix has agreed that its board of directors will nominate one individual designated by each of J.P. Morgan and APAX to the slate of nominees recommended by the board of directors to the stockholders at each annual meeting of the stockholders.

### Warrants:

During 1997, Symphonix issued warrants in connection with obtaining its equipment lease line of credit to purchase up to 26,889 shares of common stock at \$1.38 per share and up to 6,722 shares of common stock at \$5.50 per share. In June 2000, the warrant to purchase 26,889 shares of common stock was net exercised resulting in 17,493 shares of common stock being issued by Symphonix. The remaining warrants are exercisable until October 2004. The fair value of these warrants determined using the Black-Scholes option pricing model was not material, and accordingly, no value was ascribed to them for financial reporting purposes.

### Notes Receivable:

In 1997 and 1996, Symphonix issued a total of 545,000 shares of its common stock to key persons in exchange for full recourse promissory notes totaling \$484,000. The 1997 and 1996 promissory notes bear annual interest ranging from 6.36% to 6.84%, payable in the years 2001 and 2002. The related shares are pledged as collateral for the notes. The total amount outstanding due and payable in 2002 is \$175,000.

During June 1999, Symphonix issued notes receivable to a key employee in the amount of \$370,000. The note bore annual interest at 5.19% and was collateralized by 1,025,582 shares of Symphonix's common stock, but was repaid in July 2000. Additionally in August 1999, a key employee exercised 100,000 options to purchase common stock in exchange for a full recourse note receivable in the amount of \$225,000 and a restricted stock agreement. The note bears annual interest at 5.96% and is due upon the earlier of (a) August 2004, (b) 30 days following the sale of the common stock which is equal in value to the principal amount of the note or (c) 12 months following the date of termination of employment with Symphonix. The restricted stock agreement grants Symphonix repurchase rights which lapse upon attainment of full vesting, which is scheduled to occur in August 2004. At December 31, 2001 and 2000, 41,675 and 66,671 shares of common stock are subject to repurchase by Symphonix, respectively. The related shares are pledged as collateral for the note.

### Deferred Compensation:

The difference between the exercise price and the deemed fair market value of Symphonix's common stock at the date of issuance of certain stock options, totaling \$2.3 million, has been recorded as deferred compensation as a component of stockholders' equity. Of this amount, \$34,000, \$295,000, and \$517,000 has been amortized to expense in 2001, 2000 and 1999, respectively. During 2001, 2000 and 1999, Symphonix reversed none, \$411,000 and \$260,000, respectively, of unrecognized deferred compensation relating to employees that have terminated employment with Symphonix.

### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)

### 1997 Employee Stock Purchase Plan:

Symphonix adopted the 1997 Employee Stock Purchase Plan (the "Purchase Plan") under which 275,000 shares of common stock were initially reserved for issuance. During 2000, an additional 200,000 shares were reserved.

Eligible employees may purchase a limited number of common stock at 85% of the market value at certain plan-defined dates. Shares purchased under the Purchase Plan are as follows:

2001	 217,765
2000	 83,863
1999	 79,643

### 1994 Stock Option Plan:

The 1994 Stock Option Plan (the "1994 Plan") provides for grants of incentive stock options to employees (including officers and employee directors) and nonstatutory stock options to employees (including officers and employee directors) and consultants of Symphonix. The 1994 Plan is administered by a committee appointed by the Board of Directors which identifies optionees and determines the terms of options granted, including the exercise price, number of shares subject to the option and the exercisability thereof.

The terms of options granted under the 1994 Plan generally may not exceed ten years. The term of all incentive stock options granted to an optionee who, at the time of grant, owns stock representing more than 10% of the voting power of all classes of stock of Symphonix or a parent or subsidiary of Symphonix (a "Ten Percent Stockholder"), may not exceed five years. Generally, options granted under the 1994 Plan vest become exercisable starting one year after the date of grant, with 25% of the shares subject to the option becoming exercisable at that time and an additional 1/48th of such shares becoming exercisable each month thereafter. Other option grants become exercisable at 1/48th each month immediately after grant. Certain holders of options granted under the 1994 Plan may exercise their unvested options prior to complete vesting of shares, subject to such holder's entering a restricted stock purchase agreement granting Symphonix an option to repurchase, in the event of a termination of the optionee's employment or consulting relationship, any unvested shares at a price per share equal to the original exercise price per share for the option. The exercise price of incentive stock options granted under the 1994 Plan must be at least equal to the fair market value of the shares on the date of grant. The exercise price of nonstatutory stock options granted under the 1994 Plan is determined by the Board of Directors with specific criteria. The exercise price of any incentive stock option granted to a Ten Percent Stockholder must equal at least 110% of the fair market value of the common stock on the date of grant.

### SYMPHONIX DEVICES, INC. NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)

Activity under the 1994 Plan is as follows (in thousands, except per share data):

	Shares			
	Available For Grant	Number of Shares	Exercise Price	
Balance, December 31, 1998	244	660	\$0.14-\$ 4.13	
Additional options reserved	1,500			
Options granted	(1,259)	1,259	\$2.25-\$ 3.88	
Options exercised		(162)	\$0.14-\$ 2.25	
Options canceled	53	(53)	\$0.73-\$ 3.13	
Balance, December 31, 1999	538	1,704	\$0.14-\$ 4.13	
Additional options reserved	1,000			
Options granted	(1,562)	1,562	\$1.88-\$5.88	
Options exercised	_	(77)	\$0.14-\$4.13	
Shares repurchased	134		\$ 0.80	
Options canceled	274	(274)	\$0.73-\$5.06	
Balance, December 31, 2000	384	2,915	\$0.14-\$5.88	
Additional options reserved	1,000	_		
Options granted	(2,003)	2,003	\$0.76-\$1.56	
Options exercised	_	(172)	\$0.14-\$2.63	
Options canceled	1,320	(1,320)	\$0.55-\$5.88	
Balance, December 31, 2001	<del>701</del>	3,426	\$0.14-\$5.88	

The options outstanding and currently exercisable by exercise price at December 31, 2001 are as follows:

	Options outstanding			Options currently exercisable		
Exercise Price	Number Outstanding	Weighted Average Remaining Contractual Life (years)	Weighted Average Exercise Price	Number Exercisable	Weighted Average Exercise Price	
\$0.14	37	2.92	\$0.14	37	\$0.14	
\$0.55-\$0.83	1,571	9.54	\$0.76	133	\$0.75	
\$1.03-\$2.20	704	9.02	\$1.62	115	\$1.70	
\$2.25	550	7.59	\$2.25	321	\$2.25	
\$2.56-\$3.75	291	7.96	\$3.44	129	\$3.18	
\$3.84-\$5.88	_273	8.27	\$4.51	118	\$4.50	
	3,426	8.81	\$1.70	853	\$2.30	

At December 31, 2000 and 1999, outstanding options to purchase 2,915,000 and 379,000 shares were exercisable at weighted average exercise prices of \$2.76 and \$1.62 per share, respectively.

### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)

Symphonix has adopted the disclosure only provision of SFAS 123. Accordingly, Symphonix applies APB 25 and related interpretations in accounting for its stock option plan. If Symphonix had elected, beginning in 1996, to recognize compensation cost based on the fair value of the options granted at the grant date as prescribed by SFAS 123, net loss and basic and diluted net loss per common share would have been increased to the pro forma amounts shown below (thousands except per share data):

	Year Ended December 31,			
	2001	2000	1999	
Net loss as reported	\$(16,729)	\$(17,157)	\$(16,679)	
Net loss pro forma	\$(17,977)	\$(18,645)	\$(17,152)	
Basic and diluted net loss per common share as reported	\$ (0.60)	\$ (1.18)	\$ (1.35)	
Basic and diluted net loss per common share pro forma	\$ (0.65)	\$ (1.28)	\$ (1.38)	

The above pro forma disclosures are not likely to be representative of the effects on net income (loss) and basic and diluted net income (loss) per share in future years, because they do not take into consideration pro forma compensation expense related to grants made prior to 1996.

The fair value of each option grant is estimated on the date of grant using the Black-Scholes option pricing model with the following weighted average assumptions:

	2001	2000	1999
Expected dividend yield	0.0%	0.0%	0.0%
Risk-free interest rate	4.19%	6.08%	5.77%
Expected volatility	154.0%	121.1%	110.0%
Expected life (in years)	5.0	5.0	5.0

The weighted average grant date fair values of employee stock options granted during 2001, 2000, and 1999 were \$0.86, \$2.71, and \$2.14 per share, respectively.

The fair value of each Purchase Plan share is estimated on the date of issuance using the Black-Scholes option pricing model with the following weighted average assumptions:

	2001	2000	1999
Expected dividend yield	0.0%	0.0%	0.0%
Risk-free interest rate	2.49%	5.82%	4.86%
Expected volatility	154.0%	124.0%	110.0%
Expected life (in years)	0.5	0.5	0.5

The weighted average grant date fair value of the Purchase Plan shares issued during 2001, 2000 and 1999 were \$0.31, \$2.39 and \$1.29 per share, respectively.

### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)

### 7. Income Taxes:

The tax effects of temporary differences that give rise to significant portions of the deferred tax assets and liabilities at December 31, 2001 and 2000 are presented below (in thousands):

	2001	2000
Net operating loss carryforward	\$ 27,751	\$ 21,378
Depreciation	358	229
Capitalized start-up costs	319	598
Research and development credits	2,336	2,023
Deferred revenue	292	553
Accrued liabilities	1,085	857
Capitalized research and development	689	211
Valuation allowance	(32,830)	(25,849)
	<u>\$</u>	<u>\$</u>

During 2001, 2000 and 1999, the valuation allowance was increased by \$6,981,000, \$7,998,000 and \$4,592,000, respectively. Due to the uncertainties surrounding the realization of deferred tax assets, the Company has provided a full valuation allowance in all periods.

At December 31, 2001, Symphonix has \$74,932,000 of federal and \$38,985,000 of state net operating loss carryforwards which expire from 2009 through 2021 and 2002 through 2011, respectively, if not utilized.

The Tax Reform Act of 1986 limits the use of net operating loss and tax credit carryforwards in certain situations where changes occur in the stock ownership of a company. In the event Symphonix has had a change in ownership, utilization of the carryforwards could be restricted.

### 8. Employee Benefit Plan:

During 1996, Symphonix established a Retirement Savings and Investment Plan (the "Plan") under which employees may defer a portion of their salary up to the maximum allowed under IRS rules. Symphonix has the discretion to make contributions to the Plan. As of December 31, 2001, no Company contributions have been made to the Plan.

### 9. Restructuring Charge:

In November 2000, Symphonix approved plans to restructure its operations in order to accelerate the Marketing and Distribution Agreement signed with Siemens in December 1999. In the fourth quarter of 2000, Symphonix recorded a charge of \$509,000 in connection with the restructuring. The following table sets forth certain details associated with the net reorganization charges as of December 31, 2001 (in thousands of dollars):

	Restructuring Accrual at Dec. 31, 2000	Cash Payments	Adjustments	Restructuring Accrual at Dec. 31, 2001
Severance and benefits	\$262	\$(165)	\$ (97)	\$
Facility charges	111	(45)	(66)	
Other	136	(136)		
	\$509	\$ 346	<u>\$(163)</u>	\$

### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)

Severance and benefits represent the reduction of 10 sales and marketing employees in Europe. Write-off of assets consisted primarily of computer equipment, furniture, and fixtures. These assets were written off because they were excess and could not be used in any other Symphonix facility since the cost of moving the assets would be greater than the net book value of the assets. Facility charges include early termination costs associated with the closing of the international sales office. Cash payments relating to these accruals were paid in the first half of 2001. In the three month periods ended March 31, 2001 and September 30, 2001, Symphonix reversed \$82,000 and \$81,000, respectively, of excess reorganization charges related to severance and facility charges which are included in selling, general and administrative expenses in the statement of operations.

### 10. Related Party Transactions:

As of January 1, 2001, Siemens, a holder of 2,026,062 shares of Symphonix's common stock was granted full distribution rights to the European market for a 5 year period in connection with the acceleration of provisions within the Marketing and Distribution Agreement signed in November 1999. For the years ended December 31, 2001, 2000 and 1999 Siemens accounted for 48.3%, 42.6% and 3.6%, respectively, of Symphonix's revenues and as of December 31, 2001 and 2000 Siemens accounted for 60.0% and 71.9% of Symphonix's accounts receivable. For the years ended December 31, 2001, 2000 and 1999, Symphonix paid Siemens \$188,000, \$279,000 and \$48,000, respectively, under a related supply agreement.

### 11. Industry Segments:

Symphonix operates in one business segment: the design, manufacture, and sale of implantable and semi-implantable hearing devices. Currently, Symphonix markets its products to customers in the United States and Europe.

One customer accounted for 48.3% and 42.6% of Symphonix's revenue during 2001 and 2000, respectively. Five customers individually accounted for 17.5%, 17.4%, 14.1%, 13.0% and 11.2%, respectively, of Symphonix's revenue during 1999.

	Revenues			Lo	ng-lived As	sets
	2001	2000	1999	2001	2000	1999
Europe	\$1,353	\$1,086	\$323	\$ —	\$ 13	\$ 53
United States	667	161	_	1,313	1,383	1,501
Latin America			8			
	\$2,020	\$1,247	\$331	\$1,313	\$1,396	\$1,554

### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)

### 12. Selected Quarterly Financial Data (Unaudited):

The following table sets forth selected unaudited financial information for Symphonix for the eight quarters in the period ended December 31, 2001. This information has been prepared on the same basis as the audited financial statements and, in the opinion of management, contains all adjustments necessary for a fair presentation thereof.

	Quarter Ended			
	03/31	06/30	09/30	12/31
	(In thou	sands, excep	t per share a	mounts)
2001:				
Revenues	\$ 576	\$ 435	\$ 535	\$ 474
Operating loss	(5,106)	(5,228)	(4,030)	(3,158)
Net loss	(4,853)	(5,067)	(3,788)	(3,021)
Basic and diluted net loss per common share	\$ (0.23)	\$ (0.24)	\$ (0.11)	\$ (0.09)
Basic and diluted weighted average shares outstanding	20,974	21,061	33,399	35,537
2000:				
Revenues	\$ 218	\$ 195	\$ 293	\$ 541
Operating loss	(4,377)	(4,186)	(4,108)	(4,949)
Net loss	(4,297)	(4,111)	(4,080)	(4,669)
Basic and diluted net loss per common share	\$ (0.32)	\$ (0.31)	\$ (0.30)	\$ (0.26)
Basic and diluted weighted average shares outstanding	13,357	13,406	13,475	18,113

### ITEM 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND

### FINANCIAL DISCLOSURE.

There have been no disagreements with the independent accountants on accounting and financial disclosure.

On January 22, 2001, PricewaterhouseCoopers LLP resigned as the independent accountant of Symphonix Devices, Inc. The reports of PricewaterhouseCoopers LLP on the financial statement for the past two fiscal years contained no adverse opinion or disclaimer of opinion and were not qualified or modified as to uncertainty, audit scope or accounting principle. In connection with its audits for the two most recent fiscal years and through January 22, 2001, there have been no disagreements with PricewaterhouseCoopers LLP on any matter of accounting principles or practices, financial statement disclosure, or auditing scope or procedure, which disagreements if not resolved to the satisfaction of PricewaterhouseCoopers LLP would have caused them to make reference thereto in their reports on the financial statements for such years. During the two most recent fiscal years and through January 22, 2001, there have been no reportable events (as defined in Regulation S-K Item 304 (a) (1) (v)).

On February 9, 2001, the Registrant engaged KPMG LLP as its new independent accountants to audit its financial statements as of and for the year ended December 31, 2000. During the years ended December 31, 1999 and 2000 and between January 1, 2001 and February 9, 2001 the Registrant did not consult with KPMG LLP regarding the application of accounting principles to a specified transaction either completed or proposed; the Registrant did not consult with KPMG LLP regarding the type of audit opinion that might be rendered or the Registrants' financial statements; and there was not any written or oral advice provided to the Registrant prior to KPMG LLP's retention as the Registrant's independent account.

On April 2, 2001, the Registrant dismissed KPMG LLP as its independent accountants. The Registrant's Audit Committee and Board of Directors participated in and approved the decision to change the independent accountants. The reports of KPMG LLP on the financial statements for fiscal year 2000 contained no adverse opinion or disclaimer of opinion or was qualified or modified as to uncertainty, audit scope or accounting principle. In connection with its audit for the last fiscal year and through April 2, 2001, there were no disagreements with KPMG LLP on any matter of accounting principles or practices, financial statement disclosure, or auditing scope or procedure, which disagreements if not resolved to the satisfaction of KPMG LLP would have caused them to make reference thereto in their report on the financial statements for such year. During the last fiscal year and through April 2, 2001, there have been no reportable events (as defined in Regulation S-K Item 304 (a) (1) (v)).

The Registrant engaged PricewaterhouseCoopers LLP as its new independent accountants on April 9, 2001. Prior to that date, PricewaterhouseCoopers LLP audited Symphonix's financial statements from inception through December 31, 1999. PricewaterhouseCoopers LLP was the Registrant's independent accountants until January 22, 2001, at which time PricewaterhouseCoopers LLP resigned. From January 22, 2001 to April 9, 2001, the Registrant had not consulted with PricewaterhouseCoopers LLP regarding either (i) the application of accounting principles to a specified transaction, either completed or proposed; or the type of audit opinion that might be rendered on the Registrant's financial statements, and neither a written report was provided to the Registrant or oral advice was provided that PricewaterhouseCoopers LLP concluded was an important factor considered by the Registrant in reaching a decision as to an accounting, auditing or financial reporting issue; or (ii) any matter that was either the subject of a disagreement, as that term is defined in Item 304(a)(1)(iv) of Regulation S-K and the related instructions to Item 304 of Regulation S-K, or a reportable event, as that term is defined in Item 304(a)(1)(v) of Regulation S-K.

### ITEM 10. DIRECTORS AND EXECUTIVE OFFICERS OF THE REGISTRANT

Reference is made to the information regarding Directors appearing under the heading "Election of Directors" in the Registrant's proxy statement to be filed with the Commission in connection with the annual meeting of stockholders intended to be held on April 24, 2002, which information is hereby incorporated by reference. The executive officers of the Registrant, and their ages as of March 1, 2002, are as follows:

Name	Age	Position
Kirk B. Davis	44	Chairman, President and Chief Executive Officer
Geoffrey R. Ball	38	Vice President, Chief Technical Officer and Director
Terence J. Griffin	39	Vice President, Finance and Chief Financial Officer
Deborah A. Arthur	51	Vice President, Clinical Affairs
Carlos A. Baez	41	Vice President, Research and Development
Dennis S. Roy	51	Vice President, Sales & Marketing

Kirk B. Davis has served as President and Chief Executive Officer since August 1999 and Chairman since May 2000. From October 1987 to August 1999, Abbott Laboratories employed Mr. Davis most recently as Vice President and General Manager, critical care products. From 1996 to 1998 he served as General Manager of Abbott Laboratories UK operations and from 1994 to 1998 he served as Divisional Vice President and Regional Director, Europe for Abbott. Mr. Davis has a BS degree from Stanford University and an MBA degree from J.L. Kellogg Graduate School of Management at Northwestern University.

Geoffrey R. Ball invented the FMT, co-founded Symphonix and has served as Vice President and Chief Technical Officer and a director since May 1994. From 1987 to March 1994, Mr. Ball was a biomedical engineer in the hearing research laboratory at the Veterans Hospital in Palo Alto, California, affiliated with Stanford University. Mr. Ball holds an MS degree in systems management from the University of Southern California and a BS degree in human development and performance from the University of Oregon.

Terence J. Griffin has served as Vice President of Finance and Chief Financial Officer of Symphonix since April 2000. From March 1999 to March 2000, Mr. Griffin was the CFO for Zangle, a web-based information site targeting parents of school age children. Prior to that, from August 1993 to February 1999, Mr. Griffin served as CFO of Insync Systems, Inc., a provider of subsystems to the semiconductor industry and now owned by US Filter/Vivendi SA. From September 1986 to July 1993, Mr. Griffin served in a number of senior level financial management positions with Diasonics, a medical imaging and device manufacturer formerly NYSE traded and now owned by General Electric. Mr. Griffin began his career with Arthur Andersen & Co. and holds a BA in Accounting from Loyola Marymount University.

Deborah A. Arthur has served as Vice President of Clinical and Regulatory Affairs of Symphonix since February 2001 and served as VP of Clinical Affairs since August 1998. From 1990 to August 1998, Ms. Arthur was employed by the Ear Nose and Throat Division of Smith & Nephew, Inc., a leading supplier of ear, nose and throat medical devices. At Smith & Nephew, Ms. Arthur served in a variety of management positions in clinical affairs, regulatory affairs and quality assurance, including from June 1993 to July 1996 as Group Manager of Regulatory and Clinical Affairs, from July 1996 to January 1998 as Group Manager of Regulatory and Clinical Affairs and Quality Assurance, and from January 1998 to August 1998, as Director of Regulatory and Clinical Affairs and Quality Assurance. Ms. Arthur holds a BS degree in speech and hearing science from East Tennessee State University and an MA degree in audiology from the University of Tennessee.

Carlos A. Baez has served as Vice President of Research and Development of Symphonix since February 2001. From April 1998 to November 2000, Mr. Baez was Vice President of Engineering at Decibel Instruments, a U.S. hearing aid manufacturer and distributor. From March 1987 to April 1998, Mr. Baez was Director of

microelectronics at Resound Corporation, a leading manufacturer and distributor of high-technology hearing aids and now owned by Great Nordic. From May 1981 to October 1985, Mr. Baez worked at AT&T Bell Laboratories a worldwide leader in telecommunications, developing audio processing integrated circuits for cellular telephones and other communication devices including hearing aids. Mr. Baez holds a BS degree in Electrical Engineering from Columbia University and an MS degree in Electrical Engineering from the University of California, Berkeley.

Dennis S. Roy joined Symphonix in July, 2001, as Vice President of Marketing, and in December, 2001, was named Vice President, Sales and Marketing. Immediately prior to joining Symphonix, Mr. Roy was Vice President—Business Unit Leader for GE Financial Assurance-Partnership Marketing Group. From June 1988 to February 1999, Mr. Roy served in a variety of marketing, advertising, sales and P&L management positions for Beltone Electronics Corp., a leading manufacturer of hearing aids and hearing testing equipment. At Beltone, Mr. Roy served as Director of Marketing Services, Director of Strategic Planning, Vice President—North American Marketing, and Vice President—Business Planning. Earlier in his career, Mr. Roy worked for NW Ayer Advertising, The Quaker Oats Company, and Euro Tatham RSCG Advertising. He has an MBA in Marketing and a BA in Economics from the University of Michigan.

Section 16(a) of the Exchange Act requires the Company's executive officers and directors, and persons who own more than ten percent of a registered class of the Company's equity securities to file reports of ownership and changes in ownership with the Securities and Exchange Commission ("SEC") and the National Association of Securities Dealers, Inc. Executive officers, directors and greater than ten percent stockholders are required by SEC regulation to furnish the Company with copies of all Section 16(a) forms they file. Based solely on its review of the copies of such forms received by it, or written representations from reporting persons, the Company believes that, during the fiscal year ended December 31, 2001, all such forms were filed on a timely basis, except that Dennis Roy, an officer, did not timely file a Form 3 upon becoming an officer and did not file a Form 4 reporting open market acquisitions in six separate transactions, and Carlos Baez, an officer, did not timely file a Form 3 upon becoming an officer.

### ITEM 11. EXECUTIVE COMPENSATION

Reference is made to the information regarding executive compensation appearing under the heading "Executive Compensation and Other Matters" in the Registrant's proxy statement to be filed with the Commission in connection with the annual meeting of stockholders currently planned to be held on April 24, 2002, which information is hereby incorporated by reference.

### ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT

Reference is made to the information regarding security ownership appearing under the heading "Record Date and Principal Share Ownership" in the Registrant's proxy statement to be filed with the Commission in connection with the annual meeting of stockholders currently planned to be held on April 24, 2002, which information is hereby incorporated by reference.

### ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS

In November 1999, Siemens purchased 1,000,000 shares of Symphonix common stock for \$5,000,000 in a first closing pursuant to a private placement consummated in connection with a marketing and distribution agreement entered into with Symphonix. In September 2000 in accordance with the marketing and distribution agreement, Siemens purchased an additional 1,026,062 shares of Symphonix's common stock at a purchase price of \$4.87 per share resulting in gross proceeds of \$5,000,000.

As of December 31, 2001, Siemens owed Symphonix \$196,000 under the marketing and distribution agreement. For the year ended December 31, 2001, Siemens paid Symphonix \$1,006,000 under the marketing

and distribution agreement, and Symphonix paid Siemens \$188,000 under the supply agreement. The nature and terms of the original and revised marketing and distribution agreements, as well as a related supply agreement, with Siemens are as follows:

- Symphonix entered into the marketing and distribution agreement in February 1999 and entered into the supply agreement in June 1999.
- Under the marketing and distribution agreement, Symphonix agreed to conduct collaborative marketing efforts, and Siemens has exclusive distribution rights in Europe for existing Symphonix products and any future product introductions.
- The marketing and distribution agreement has a term ending on December 1, 2004 and is subject to automatic annual renewals thereafter unless terminated by either party with at least 12 months' notice. If Symphonix does not renew the marketing and distribution agreement, it is obligated to pay Siemens the equivalent of Siemens' revenues with Symphonix products in Europe during the preceding twelve months.
- The marketing and distribution agreement may also be terminated at any time if Symphonix is acquired at the option of: (i) Symphonix, with three month's notice and payment to Siemens of (A) \$1 million or 200% of Siemens' revenue in Europe with Symphonix products during the 12 months preceding the acquisition if the agreement is terminated before December 1, 2001, (B) \$1 million or 150% of Siemens' revenue in Europe with Symphonix products during the 12 months preceding the acquisition if the agreement is terminated between December 1, 2001 and December 1, 2002, or (C) \$2 million or 100% of Siemens' revenue in Europe with Symphonix products during the 12 months preceding the acquisition if the agreement is terminated between December 1, 2002 and December 1, 2004; or (ii) Siemens, if Symphonix is acquired by a manufacturer of acoustic hearing aids.
- The marketing and distribution agreement may also be terminated at the option of either party in the event of a material breach that is not cured within 30 days of notice of breach, or upon the insolvency or bankruptcy of either party.
- Under the terms of the supply agreement, Siemens agreed to supply integrated circuits and software for use in Symphonix's Soundbridge products.
- The supply agreement has a term ending on September 30, 2004 and is subject to automatic annual renewals thereafter unless terminated by either party with at least three months' notice. The supply agreement may also be terminated at any time in the event of a material breach that is not cured within 30 days of notice of breach.

On November 10, 2000, Symphonix issued an aggregate of 6,397,632 shares of its common stock to investors for a purchase price of approximately \$26,000,000, which represented a per share price of \$4.064. The Common Stock Purchase Agreement, under which the shares were sold, provided for a purchase price adjustment that allowed the investors to calculate, one time prior to November 10, 2002, an adjusted per share purchase price equal to the average closing market price of Symphonix common stock as reported on the NASDAQ National Market for the 33 consecutive trading days immediately preceding the date of adjustment. Those investors participating in the adjustment would receive additional shares of common stock, for no additional consideration, equal to the difference between the number of shares which each investor could have purchased based on the adjusted per share purchase price at the investor's original investment amount and the number of shares originally purchased.

The investors in the transaction included three trusts of which B.J. Cassin, one of Symphonix's directors, is a trustee. Symphonix issued and sold an aggregate of 246,061 shares of its common stock to the trusts in the transaction for a purchase price of approximately \$999,992. In connection with the issuance of 2,460,630 shares to each of J.P. Morgan Capital and APAX, Symphonix agreed that its board of directors will nominate one individual designated by each of J.P. Morgan and APAX to its board of directors, and that its board of directors

and management will vote all shares for which they hold proxies or otherwise are entitled to vote in favor of these nominees. Martin Friedman, a nominee of J.P. Morgan, and Adele Oliva, a nominee of APAX, have been serving on the board of directors since the closing of the transaction.

On June 25, 2001, certain investors notified Symphonix that they were exercising their purchase price adjustment pursuant to the Common Stock Purchase Agreement. All investors agreed to participate in the adjustment, and on July 12, 2001, Symphonix subsequently issued, for no additional consideration, an additional 14,336,020 shares to the investors based on an adjusted per share purchase price of approximately \$1.254.

Symphonix believes that this transaction was made on terms no less favorable to Symphonix than could have been obtained from unaffiliated third parties. All future transactions, including loans, between Symphonix and its officers, directors, principal stockholders and their affiliates will be approved by a majority of the board of directors, and will continue to be on terms no less favorable to Symphonix than could be obtained from unaffiliated third parties.

### PART IV

### ITEM 14. EXHIBITS, FINANCIAL STATEMENT SCHEDULES AND REPORTS ON FORM 8-K

- (a) The following documents are filed in Part II of this Annual Report on Form 10-K.
- 1. Financial Statements

	Page No.
Report of Independent Accountants	33
Report of Independent Auditors	34
Consolidated Balance Sheets at December 31, 2001 and 2000	35
Consolidated Statements of Operations for the years ended December 31, 2001, 2000 and 1999	36
Consolidated Statements of Cash Flows for the years ended December 31, 2001, 2000 and 1999	37
Consolidated Statements of Stockholders' Equity for the years ended December 31, 2001, 2000 and 1999	38
Consolidated Statements of Comprehensive Loss for the years ended December 31, 2001, 2000 and 1999	39
Notes to Consolidated Financial Statements	40

2. Financial Statement Schedules. The following consolidated financial statement schedule of Symphonix Devices, Inc. for the year ended December 31, 2001 is filed as part of this Report and should be read in conjunction with the consolidated financial statements:

Description	Page No.
Schedule II—Valuation and Qualifying Accounts	62

Schedules not listed above have been omitted because they are not applicable or are not required to be set forth therein is included in the consolidated financial statements or notes thereto.

(b) Reports on Form 8-K

None

### (c) Exhibits.

Exhibit	Description
3.1*	Certificate of Incorporation of Symphonix Devices, Inc., a Delaware corporation, as currently in effect.
3.2*	Bylaws of the Registrant, as currently in effect.
3.3*	Certificate of Amendment of the Certificate of Incorporation of the Registrant, amending Exhibit 3.1.
4.1*	Specimen Common Stock Certificate.
10.1*	Form of Indemnification Agreement between the Registrant and each of its directors and officers.
10.2*	1994 Stock Option Plan and forms of Stock Option Agreements thereunder.
10.3*	1998 Employee Stock Purchase Plan.
10.4*	Restated Investors Rights Agreement dated June 11, 1997 between the Registrant and certain holders of the Registrant's securities.
10.5*	Master Equipment Lease Agreement between the Registrant and Lighthouse Capital Partners dated December 2, 1994.
10.6*	Assignment by the Registrant to VibRx, Inc. dated March 14, 1997.
10.7*	Registrant's Series D Preferred Stock Purchase Agreement dated June 11, 1997.
10.8*	Net Lease Agreement between Realtec Properties I, L.P., a California limited partnership, and the Registrant dated July 28, 1994; letter agreements dated July 28, 1994 and August 17, 1994 and First Amendment dated April 17, 1997.
10.9*	Lease between Silicon Valley Properties, L.L.C., a Delaware limited liability partnership, and the Registrant dated October 27, 1997.
10.10*	Form of Option Vesting Agreement between the Registrant and its officers.
10.11*	License Agreement dated June 1, 1995 between Baptist Medical Center of Oklahoma, Inc. and the Registrant.
10.12*	Loan and Security Agreement dated December 30, 1997 between the Registrant and Silicon Valley Bank.
10.13(1)	Loan Modification Agreement dated December 24, 1998 between the Registrant and Silicon Valley Bank.
10.14(1)	Premium Contribution Plan Effective November 1, 1998, as Amended and Restated on January 1, 1999.
10.15(1)	Form of Distribution Agreement.
10.16**(2)	Joint Development and Supply Agreement dated January 16, 1998 between the Registrant and Topholm & Westermann Aps and the subsequent Amendment thereto effective November 30, 1998.
10.17(3)	Loan and Security Agreement with an attached Non-Recourse Secured Promissory Note dated June 29, 1999 between the Registrant and Harry S. Robbins.
10.18(4)	OEM and Supply Agreement dated June 4, 1999 between the Registrant and Siemens Audiologische Technik GmbH ("Siemens").
10.19(5)	Marketing and Distribution Agreement dated November 2, 1999 between the Registrant and Siemens.
10.20(5)	Common Stock Purchase Agreement dated December 1, 1999 between the Registrant and Siemens.
10.21(6)	Common Stock Purchase Agreement dated September 18, 2000 between Symphonix and certain investors, including exhibits
21.2	List of Subsidiaries of the Registrant.
23.1	Consent of PricewaterhouseCoopers LLP, independent accountants.
23.3	Consent of KPMG LLP, independent auditors.
24.1	Power of Attorney (see page 63).

- \* Filed as an Exhibit to the Registrant's Registration Statement on Form S-1 (File No. 333-40339) and incorporated herein by reference.
- \*\* Confidential treatment requested.
- (1) Filed as an exhibit to the Registrant's Annual Report on Form 10-K for the fiscal year ended December 31, 1998.
- (2) Filed as exhibits to the Registrant's report on Form 10-Q for the fiscal quarter ending March 31, 1999, and incorporated herein by reference.
- (3) Filed as an exhibit to the Registrant's report on Form 10-Q for the quarter ending June 30, 1999 and incorporated herein by reference.
- (4) Filed as an exhibit to the Registrant's report on Form 10-Q for the fiscal quarter ended September 30, 1999 and incorporated herein by reference.
- (5) Filed as an exhibit to the Registrant's report on Form 8-K filed with the Securities and Exchange Commission on December 20, 1999 and incorporated herein by reference.
- (6) Filed as an exhibit to the Registrant's report on Form 8-K filed with the Securities and Exchange Commission on November 2, 2000 and incorporated herein by reference.

### SCHEDULE II—VALUATION AND QUALIFYING ACCOUNTS (In thousands)

	Balance at beginning of period	Additions	Deductions	Balance at end of period
Allowance for doubtful accounts:				
Year ended December 31, 2001	\$ 7	\$ 20	\$—	\$27
Year ended December 31, 2000	55		48	7
Year ended December 31, 1999	\$ 3	\$ 52	<b>\$</b> —	\$55
	Balance at beginning of period	Additions	Deductions	Balance at end of period
Warranty provision:	beginning	Additions	Deductions	end of
Warranty provision: Year ended December 31, 2001	beginning	Additions \$ —	Deductions \$ 279	end of
	beginning of period			end of period

### SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized, in the City of San Jose, State of California, on the 27th day of March, 2002.

SYMPHONIX DEVICES, INC.

Bv:	/s/ Kirk B. Davis				
-,	Kirk B. Davis				
Chairman, President, Chief Executive Officer and					
	Dinastan				

### POWER OF ATTORNEY

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints Kirk B. Davis and Terence Griffin, and each of them, his attorneys-in-fact, and agents, each with the power of substitution, for him and in his name, place and stead, in any and all capacities, to sign any and all amendments to this Report on Form 10-K, and all documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorneys-in-fact and agents, and each of them, full power and authority to do and perform each and every act and thing requisite and necessary to be done in and about the premises, as fully to all intents and purposes as he might or could do in person, hereby ratifying and conforming all that said attorneys-in-fact and agents of any of them, or his or their substitute or substitutes, may lawfully do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons in the capacities and on the dates indicated.

Signature	Title	Date
/s/ KIRK B. DAVIS Kirk B. Davis	Chairman, President, Chief Executive Officer and Director (Principal Executive Officer)	March 27, 2002
/s/ TERENCE J. GRIFFIN Terence J. Griffin	Vice President, Finance and Chief Financial Officer (Principal Financial and Accounting Officer)	March 27, 2002
/s/ GEOFFREY R. BALL Geoffrey R. Ball	Vice President and Chief Technology Officer	March 27, 2002
/s/ B. J. Cassin B. J. Cassin	Director	March 27, 2002
/s/ Martin Friedman  Martin Friedman	Director	March 27, 2002
/s/ ADELE OLIVA Adele Oliva	Director	March 27, 2002
/s/ ROGER RADKE  Roger Radke	Director	March 27, 2002

### BOARD OF DIRECTORS

Geoff Ball

Founder and Chief Technology Officer

B.J. Cassin

A Venture Capitalist and Chairman of the Board of Cerus Corporation A Medical Device Company

Kirk Davis

Chairman, Chief Executive Officer and President

Martin Friedman

Vice President, JP Morgan Partners A Private Equity Firm

Adele Oliva

Partner, APAX Partners A Private Equity Firm

Roger Radke, Ph.D

Managing Director Siemens Audiologische A Hearing Instrument Company

### OFFICERS

Deborah Arthur Vice President of Regulatory and Clinical Affairs

Geoff Ball

Founder and Chief Technology Officer

Kirk Davis Chairman, Chief Executive Officer and

President

Terence Griffin Vice President Finance and Chief Financial Officer

Dennis Roy

Vice President of Sales and Marketing

# INDEPENDENT PUBLIC ACCOUNTANTS

PricewaterhouseCoopers LLP San Jose, CA

### LEGAL COUNSEL

Wilson Sonsini Goodrich & Rosati Professional Corporation Palo Alto, CA

### STOCK TRANSFER AGENT AND REGISTRAR

Equiserve Trust Company Providence, RI

# ANNUAL MEETING OF STOCKHOLDERS

The annual meeting of stockholders will be at 12:00 P.M. on April 24, 2002 at the offices of:

Symphonix Devices, Inc. 2331 Zanker Road San Jose, CA 95131-1109

## STOCK MARKET LISTING

The Company's common stock is traded on the Nasdaq National Stock market under the symbol SMPX.

# SYMPHONIX PRODUCT FAMILY

AUDIO PROCESSOR



VIBRATING OSSICULAR PROSTHESIS

